

credit accident and health insurance directly related to extensions of credit, pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, July 24, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-18569 Filed 7-27-95; 8:45 am]

BILLING CODE 6210-01-F

South Banking Company; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than August 11, 1995.

A. Federal Reserve Bank of Atlanta
(Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *South Banking Company*, Alma, Georgia; to acquire 100 percent of the voting shares of Pineland State Bank, Metter, Georgia.

Board of Governors of the Federal Reserve System, July 24, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-18568 Filed 7-27-95; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL TRADE COMMISSION

Regulations under the Comprehensive Smokeless Tobacco Health Education Act of 1986; Information Collection Requirement

AGENCY: Federal Trade Commission.

ACTION: Notice of application to OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) for clearance of information collection requirements contained in the Regulations under the Comprehensive Smokeless Tobacco Health Education Act of 1986.

SUMMARY: This publication provides notice that the Federal Trade Commission is seeking renewed approval for three years from OMB for the information collection requirements contained in the Regulations under the Comprehensive Smokeless Tobacco Health Education Act of 1986. The present OMB approval for the information collection requirements is scheduled to expire on August 31, 1995.

The Smokeless Tobacco Act requires, among other things, that manufacturers, packagers, and importers of smokeless tobacco products include health warnings on packages and in advertisements. The Act also requires each manufacturer, packager, and importer of a smokeless tobacco product to submit a plan to the Commission that specifies the methods used to rotate, display, and distribute the warning statements required to appear in advertising and labeling. Section 3(d) directs the Commission to approve plans that provide for rotation, display, and distribution of the warning statements in accordance with the regulations. All the affected companies have previously filed plans, but the plan submission requirement continues to apply to a company that amends its plans, or to a new company that enters the market.

Estimate of Information Collection Burden

In 1986, staff estimates that as many as ten domestic and four foreign smokeless tobacco companies would submit plans specifying the method used to rotate, display, and distribute health warnings in their labeling and advertising. This prediction was accurate. Fourteen plans were received.

When the regulations were first proposed, representatives of the Smokeless Tobacco Council, Inc., indicated that six companies that it represented would require a total of 700 to 800 hours (or about 133 hours apiece, on average) to prepare the required plans. We also assumed that the other

companies, whose plans were prepared by other representatives, would require more time, on average, and used 150 hours per plan to account for the remainder of the expected submissions. Based on these assumptions staff estimated that no more than 2,000 hours would be spent to prepare and submit compliance plans. (Six companies total=800 hours, plus eight companies at 150 hours=1,200 hours.) The Commission provided a burden estimate to OMB of 2,000 hours for the reporting requirements.

In 1992, the Commission proposed amendments to the rotation of health warnings on point-of-sale and non-point-of-sale promotional materials. Pursuant to the proposed amendment, affected firms will have to submit new plans for Commission approval. The amendment of previously submitted plans to incorporate plans for promotional materials should require less time than was devoted to the original submissions. As in 1992, there is no substantial basis for calculating the proportion of the original burden estimate that will be attributable to the amendment process and accordingly, the Commission proposes to retain the existing burden estimate for purposes of seeking this extension.

DATES: Comments on this application must be submitted on or before August 28, 1995.

ADDRESSES: Send comments both to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3228, Washington, D.C. 20503, ATN: Desk Officer for the Federal Trade Commission, and the Office of the Secretary, Room 159, Federal Trade Commission, Washington, D.C. 20580. Copies of the application may be obtained from the Public Reference Section, Room 130, Federal Trade Commission, Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT:

Phillip S. Priesman, Attorney, Federal Trade Commission, Washington, D.C. 20580 (202) 326-2484.

Stephen Calkins,

General Counsel.

[FR Doc. 95-18595 Filed 7-27-95; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Toxic Substances and Disease Registry**

[ATSDR-96]

ATSDR's Final Criteria for Determining the Appropriateness of a Medical Monitoring Program Under CERCLA

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Public Health Service (PHS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the criteria for determining the appropriateness of a medical monitoring program under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Draft criteria were published for public comment on September 9, 1994 (59 FR 46648). The public comment period ended October 24, 1994. Comments were received from 15 individuals representing States, industry, activist groups, and environmental medicine clinics. This document reflects those comments received on the draft criteria.

ADDRESSES: Division of Health Studies, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E-31, Atlanta, Georgia 30333, telephone (404) 639-6200.

FOR FURTHER INFORMATION CONTACT: Dr. Wendy E. Kaye, Chief, Epidemiology and Surveillance Branch, Division of Health Studies, ATSDR, telephone (404) 639-6203.

SUPPLEMENTARY INFORMATION: Section 104(i)(9) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended [42 U.S.C. 9604(i)(9)], provides for the Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR) to initiate a health surveillance program for populations at significantly increased risk of adverse health effects as a result of exposure to hazardous substances released from a facility. A program included under health surveillance is referred to as "Medical Monitoring or Screening" by ATSDR and is defined in the legislation as "the periodic medical testing to screen people at significant increased risk for disease." ATSDR has established criteria to determine when medical monitoring is an appropriate health activity and the requirements for establishing a medical monitoring program at a site. The legislation also

states that a mechanism to refer people for treatment should be included in the program. Statutory language only allows ATSDR to provide medical care or treatment in cases of public health emergencies as declared by the President.

Background

ATSDR is responsible for the public health-related activities of CERCLA. ATSDR's primary initial response at a hazardous waste site is the public health assessment, which is required for every site on the National Priorities List (NPL). A public health assessment can also be conducted in response to a petition from the public. Other important components of ATSDR's initial response at sites include health consultations and public health advisories. During the process of developing the public health assessments and health advisories, ATSDR invites the participation of communities through a variety of avenues such as public meetings, public availability sessions, and Community Assistance Panels (CAPs). The documents produced by ATSDR during the process are placed in a public repository to allow the public access to the documents. The public health assessments, health consultations, and public health advisories undergo review by ATSDR to determine if follow-up health-related activities are needed for populations at risk in the affected community.

The types of follow-up health activities recommended for a site will depend on the amount of information on the possible exposures and their suspected pathways. In any case in which an association has not been established between an exposure and a specific adverse health outcome, several research and health education activities may be considered. Those activities could include health outcome studies, an exposure assessment at the site, epidemiologic studies, or professional education.

ATSDR's Division of Health Assessment and Consultation has established a program for the investigation of exposures in communities which enables a more timely response to questions on whether individuals in a community are being exposed. The program incorporates a variety of industrial hygiene techniques for measuring chemicals in the environment, as well as selected biological markers of exposure.

The Division of Health Education provides a wide variety of services to educate health care professionals and communities on the effects of exposures

to hazardous substances. Activities in a community around a hazardous waste site may include conducting grand rounds for health care providers on the effects of a specific chemical, providing fact sheets on chemicals, conducting workshops on clues to environmental disease, and producing case studies in environmental medicine.

The Division of Health Studies is responsible for conducting epidemiologic research, including several types of studies (cluster investigations, disease and symptom prevalence studies, analytic epidemiologic studies), surveillance programs, and exposure registries. Cluster investigations and disease and symptom prevalence studies investigate the occurrence of disease in populations. Analytic epidemiology studies are conducted to evaluate the causal nature of associations between exposure to hazardous substances and disease outcomes. The surveillance program focuses on exposures to substances at hazardous waste sites and includes systems that follow populations exposed to hazardous wastes because of where they live or their occupation. It also includes surveillance of emergency events in which hazardous substances are released into the environment. The National Exposure Registry maintains a listing of people exposed to hazardous substances. The Registry is composed of chemical specific subregistries. The chemicals are selected from the ATSDR/EPA priority list of hazardous substances.

Medical monitoring is considered one of several follow-up health activity options under the site-specific work conducted by ATSDR. A medical monitoring program for the community around a site will be considered with other health follow-up activities when the information from ATSDR's initial response at the site is reviewed. In cases in which there is no known association between the exposure and specific adverse health effects (which could include health outcomes, illnesses, or markers of effect), medical monitoring is not an appropriate public health activity. In cases in which there is limited information on a specific health effect's relationship to an exposure, then options such as epidemiologic surveillance, a disease and symptom prevalence study, or an epidemiologic study are more appropriate. When adequate information exists that links exposure to a chemical with a specific adverse health effect, further consideration will be given to the appropriateness of medical monitoring in that population.

Medical monitoring should be directed toward a target community identified as being at "significant increased risk for disease" on the basis of its exposure. Significant increased risk will vary for particular sites depending upon such factors as the underlying risk of the selected outcome, the risk attributable to the exposure, and the presence of sensitive subpopulations. These factors will be considered when evaluating the appropriateness of medical monitoring in a community. The CERCLA legislation also provides for a mechanism for referral for treatment of those who are screened positive for the selected health outcomes; therefore, a mechanism to refer people for diagnosis, interventions, or treatment should be in place prior to the initiation of a medical monitoring program.

The primary purpose of a medical monitoring program is not considered to be a research activity that further investigates the cause-effect relationship between exposure and outcome. The purpose of a medical monitoring program is case-finding in order to refer individuals for further evaluation and, as appropriate, treatment. Within this framework, medical monitoring includes both testing for early biological effect and an assessment of exposure using biological specimens (for example, blood or urine), when appropriate. This is provided as a service to individuals in communities where there is believed to be an increased risk of disease from exposure to hazardous substances released into the environment.

Criteria for Considering Medical Monitoring

The criteria outlined below will be used to determine the appropriateness of conducting medical monitoring in a community and will be applied in a phased approach. Phase I, conducted by ATSDR, consists of an evaluation of the exposure and outcome criteria. Phase II consists of an evaluation of the system criteria. Phase II will be conducted with the input of a panel consisting of community, State and local health officials, and ATSDR. At the end of Phase II, a detailed medical monitoring plan will be written at sites where a monitoring program is established. All of the criteria must be met at a site in order for a medical monitoring program to be established at that site. In addition, resources must be available to initiate and sustain the program.

Phase I

Exposure Criteria

A. There should be evidence of contaminant levels in environmental media that would suggest the high likelihood of environmental exposure to a hazardous substance and subsequent adverse health outcomes.

The National Research Council (NRC) defines exposure as "an event that occurs when there is contact at a boundary between a human and the environment at a specific contaminant concentration for a specified period of time; the units to express exposure are concentration multiplied by time" (NRC, 1991). The specific contaminant concentration and period of time will vary for different chemicals and different media. The exposure must be to a hazardous substance as defined under CERCLA, and the result of a release from a CERCLA-covered facility. A release from a CERCLA-covered facility includes those events that establish an open pathway of exposure (i.e., an unfenced area with high soil contamination could be considered a "release") or allows contaminants to go off-site via air, surface water, ground water, or other pathway. The primary criteria for medical monitoring should be documented evidence of exposure of a population to a hazardous substance in the environment. An exposure will be considered to be at a sufficient level if there is documentation of an increased opportunity for exposure to a level that meets or exceeds some health-based comparison value (such as Minimum Risk Levels (MRLs) or Reference Doses (RfDs)) or that meets or exceeds a level reported in the peer-reviewed literature to result in some adverse health effect. Documentation is considered sufficient if it is from an exposure assessment, environmental exposure modeling, or sampling from a general area (for example, water samples from an aquifer or a town water supply). Documentation of individual levels of exposure is not required. In cases in which exposures are unknown or undocumented, environmental monitoring is a more appropriate initial activity.

B. There should be a well-defined, identifiable target population of concern in which exposure to a hazardous substance at a sufficient level has occurred.

Initially, the target population of concern will be defined geographically on the basis of exposure. In addition, all populations considered will be assessed for the presence of any sub-population at increased risk of the adverse health effects associated with the exposures. An example of a subpopulation at

increased risk would be preschool children in an area with known lead exposures. The size of the target population of concern is not a factor in the decision for monitoring. In areas where biological markers of exposure have not been collected, environmental sampling can be used to estimate exposure levels. The target population of concern is the population in which there is documented exposure at a sufficient level to place the individuals in that population at significant increased risk for developing some specific adverse health effect.

Outcome Criteria

A. There should be documented human health research that demonstrates a scientific basis for a reasonable association between an exposure to a hazardous substance and a specific adverse health effect (such as an illness or change in a biological marker of effect).

Previous studies on human populations must demonstrate a reasonable association between a particular exposure and an adverse health effect. In order to make that inference, consideration should be given to the strength, specificity, and consistency of the association among the identified studies. The period of exposure (including the timing and duration of the exposure) and its relationship to the latency period for the disease or illness should also be examined if information is available. Consideration should be given to whether the association has demonstrated a dose-response relationship and whether the association is consistent with the existing body of knowledge. This information could include a variety of occupational, epidemiological, or other studies involving human populations.

B. The monitoring should be directed at detecting adverse health effects that are consistent with the existing body of knowledge and amenable to prevention or intervention measures.

The monitoring should be established for specific adverse health effects. The specific adverse health effect being monitored should be a result of the possible exposure consistent with the existing body of knowledge. An adverse health effect is consistent with the existing body of knowledge if it has been described in the literature as caused by that agent or by similar agents, taking into account structure-activity relations.

In addition, the adverse health effects (disease process, illness, or biomarkers of effect) should be such that early detection and treatment or intervention

interrupts the progress to symptomatic disease, improves the prognosis of the disease, improves the quality of life of the individual, or is amenable to primary prevention. If the adverse health effects that are of concern in an individual or in a community are not easily detectable and not medically treatable, then medical monitoring would not be beneficial and would not be an appropriate public health activity. An easily detectable effect is one that can be found on clinical examination, or through the use of simple, diagnostic tests in an outpatient setting. Also, the test procedures must be acceptable to the patient and the community. The diagnostic tests must be nonexperimental, relatively noninvasive (such as the drawing of a tube of blood for laboratory tests), and simple to administer.

Monitoring for Evidence of Continuing Exposure

At sites with exposure in the community, the monitoring program might include biological markers of continuing exposure. For example, the Bunker Hill Superfund site has had lead screening of children for many years. Those sites would be ones in which the exposure is known to have a variety of adverse health effects, but for which no tests are available to detect those effects at a time when intervention could affect the course of the disease process. In those instances, the primary intervention is to remove the individual from the exposure. This allows the medical monitoring system to recommend referral for intervention prior to the onset of detectable adverse health effects. A monitoring system that includes biomarkers of continuing exposure is similar to medical surveillance of hazardous waste workers where changes indicative of increasing or continued exposures occur sufficiently early that the exposure can be curtailed and the risk for disease reduced (Gochfeld 1990).

Phase II

General Information

Phase II of the program is carried out by ATSDR with assistance from the community. When ATSDR has determined that exposure from a site has met the exposure and outcome criteria, a site panel will be formed based on recommendations from the community and the State and/or local health departments to review the system criteria and to assist in the development of a site-specific medical monitoring plan. The site panel will include representatives from ATSDR, the

community, State or local health departments, local medical societies, and subject experts as necessary. The site panel will function in much the same manner as the Community Assistance Panels (CAPs) that are established at some sites during the public health assessment process. The site panel will follow the established procedures for those CAPs. The site panel will be responsible for assessing the available community health resources and determining the feasibility and extent of the screening program for the community. If the panel determines that a screening program is feasible in the community and ATSDR concurs with that decision, ATSDR will develop a site-specific monitoring plan. That plan will be presented to the site panel for review and concurrence. After the plan has been developed and has undergone peer review, it will be presented to the community at large for their input prior to establishing the program.

System Criteria

A. The general requirements for a medical screening program should be satisfied.

The monitoring aspect of a health surveillance program consists of the periodic medical testing to screen individuals who are at increased risk of disease. Monitoring serves to identify those individuals with an unrecognized adverse health effect. This is consistent with the definition of screening as "the presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to their physicians for diagnosis and necessary treatment." (Commission on Chronic Illness, 1957) In general, the ability to predict the presence or absence of disease from test results depends on the sensitivity and specificity of the test and the prevalence of the disease in the population being tested. The higher the prevalence, the more likely a positive test indicates disease (Mausner & Kramer, 1985). In order for a screening program to be of public health benefit, the population being screened should be at a significantly high risk for the undiagnosed disease (i.e., the disease should have a sufficiently high prevalence in the population).

Given that definition, there are certain requirements for screening programs

that should be considered when evaluating a possible medical monitoring program for a site (adopted from Mausner & Kramer, 1985). Those requirements are:

- ★ The natural history of the disease process should be understood sufficiently for screening.

- ★ The early detection through screening should be known to have an impact on the natural history of that disease process. For example, the detection of breast cancer while it is localized has been shown to increase the ten-year survival rate. For that reason, several groups have made recommendations for the early detection of breast cancer in asymptomatic women. Those recommendations include breast self-examination, breast physical examination, and mammography (Metzlin & Dodd, 1991; Kelsey & Gammon, 1991).

- ★ There should be an accepted screening test that meets the requirements for validity, reliability, estimates of yield, sensitivity, specificity, and acceptable cost. The purpose of ATSDR-sponsored medical monitoring is not to develop new screening tests. The medical monitoring program will use tests that have been recommended and used for screening in other settings.

The U.S. Preventive Services Task Force has established criteria for determining the effectiveness of preventive strategies including screening tests. The criteria for effectiveness of a screening test include the efficacy of the screening test and the effectiveness of early detection. The Task Force used efficacy to mean accuracy and reliability. The accuracy is measured using four indices: sensitivity, specificity, positive predictive value, and negative predictive value (see table below for definitions). A test with poor sensitivity will result in a large proportion of persons with disease being told they are free of disease (false-negatives). A test with poor specificity will result in healthy persons being told they have the disease (false-positives). There may be serious consequences in the use of screening tests with poor sensitivity and/or specificity. Persons with false negative results may have delays in diagnosis and treatment. False positive results can result in follow-up testing that is uncomfortable, expensive and potentially harmful. The evaluation and selection of a screening test must include a determination of the likelihood of producing false positive results (the positive predictive value (PPV)). The PPV changes in accordance with the prevalence of the condition in the screened population. PPV is unlike

sensitivity and specificity in that it is not a constant characteristic of a screening test. If the condition is sufficiently rare in the screened population, even tests with excellent sensitivity and specificity can have low PPV, having more false positive results than true positive results.

Another important aspect in determining the efficacy of a screening test is the reliability of the test. The reliability (reproducibility) is the ability of the test to give the same result when it is repeated. An accurate test with poor reliability can produce results that vary widely from the correct value, even

though the average of the results approximates the true value. Poor reliability may be due to either interobserver variation or intraobserver variation (U.S. Preventive Services Task Force, 1989).

DEFINITION OF TERMS

Term	Definition	Formula*
Sensitivity	Proportion of persons with the condition who test positive.	$\frac{a}{a + c}$
Specificity	Proportion of persons without the condition who test negative.	$\frac{d}{b + d}$
Positive Predictive Value	Proportion of persons with positive test who have condition.	$\frac{a}{a + b}$
Negative Predictive Value	Proportion of persons with negative test who do not have the condition.	$\frac{d}{c + d}$
*Explanation of Symbols	Condition absent	Condition present
Positive Test	a	b
Negative Test	c	d

Legend: a=true +; b=false +; c=false -; d=true -.

★ The screening program should be one that is feasible and acceptable to individuals and the community. Therefore, plans and possible screening tests for a medical monitoring program will be presented to the community for input prior to the initiation of any recommended program.

B. An accepted treatment, intervention, or both, for the condition (outcome or marker of exposure) must exist and a referral system should be in place prior to the initiation of a medical monitoring program.

There should be established criteria for determining who should receive referral for intervention or treatment. These criteria will be based on the selected effect being screened for and the screening test being used. Results will be evaluated by ATSDR longitudinally and cross-sectionally to identify changes in the system or screening tools that require follow-up (Gochfeld 1990). A referral mechanism should exist so that those who are eligible for the intervention can be referred to a qualified health care provider for further diagnosis, treatment, or intervention. The referral must be for treatment or intervention that is standard practice and not experimental in nature. The medical monitoring (screening) program is not responsible for the cost of the referral, the intervention, or the treatment of individuals participating in the program.

C. The logistics of the system must be resolved before the program can be initiated.

After medical monitoring has been determined to be appropriate for a site, the specifics of the monitoring system will be detailed in a site-specific medical monitoring plan. The site panel consisting of the community members, appropriate health officials, and subject experts as necessary will work with ATSDR to develop and review the site-specific medical monitoring plan. The specifics of the medical monitoring system recommended can vary for each site. The monitoring plan is the protocol for the specific program to be proposed in a community. The plan will outline the target community, the types of outcomes to be screened for, the participants in the referral system, and the program reports. The plan will include a review of the latency period for the outcomes being monitored and the duration of the exposure to define the period of time that the program will operate in a specific site population. The target population; the completeness with which the exposed population can be identified, contacted, and followed; the screening tests; and the selected health outcomes will all influence the specifics of the system. Existing medical facilities and personnel will be used when possible.

The monitoring plan will be submitted for peer review prior to its implementation at a site. The plan for a site might require additional review by an expert panel (ethicists, NRC) to

evaluate the screening tests recommended. ATSDR's Division of Health Studies will work closely with the Division of Health Education to provide professional health education when needed to enhance the medical monitoring program.

Medical monitoring is one of ATSDR's service activities and is not considered to be a research tool. The monitoring activity at each site will be routinely evaluated for the effectiveness of the screening tests in place and the types of effects being detected. Due to confidentiality issues in dealing with small groups of people, the reporting from the system will consist of annual reports noting the number of individuals screened, the number of referrals made, and the number of conditions diagnosed in the referral system. ATSDR will develop a list that includes information on the types of exposures seen in the communities and the types of screening tests that were included in the monitoring. ATSDR can provide this information as available to the site panels to assist them in deciding on the types of screening tools based on what has been used in other areas.

The referral system will consist of the review of the screening results and the referral to appropriate health care providers or referral physicians. The specific mechanisms for determining who needs referral and for selecting the health care providers in the referral pool must be in place prior to the initiation of the medical monitoring. Once the participant has been referred to the

referral providers, those providers will be responsible for any subsequent diagnosis, treatment, or intervention.

Summary of Medical Monitoring

Medical monitoring will be considered along with the other health follow-up activities to be recommended for populations around specific sites. The Division of Health Studies will make a determination on whether a site meets the exposure and outcome criteria for medical monitoring. If a site meets the previously discussed criteria and is selected for further consideration of a medical monitoring program, ATSDR will work with the community and other appropriate entities in designing the specific monitoring and referral system for that site's target population. ATSDR will notify, and where appropriate, work with the state health department to establish the program. The Division of Health Studies will monitor the program and be responsible for the oversight on the annual reports.

References

- Commission on Chronic Illness. *Chronic Illness in the United States*, Vol. 1. Commonwealth Fund, Harvard University Press, Cambridge, 1957, page 45.
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- Kelsey JL and MD Gammon. The epidemiology of breast cancer. *CA—A Cancer Journal for Clinicians* 1991; 41(3):146-165.
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- Mettlin C and GD Dodd. The American Cancer Society guidelines for the cancer-related checkup: An update. *CA—A Cancer Journal for Clinicians* 1991; 41(5):279-282.
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- U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services: An Assessment of the Effectiveness of 169 Interventions*. Baltimore: Williams & Wilkins, 1989, pages xxix-xxxvii. Dated: July 24, 1995.

Claire V. Broome,

Deputy Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 95-18578 Filed 7-27-95; 8:45 am]

BILLING CODE 4163-70-P

Centers for Disease Control and Prevention

[Announcement 562]

Analytic Studies to Elaborate the Impact of Race, Ethnicity, and Socioeconomic Status Upon the Health of Minority Populations

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for cooperative agreements to conduct analytic studies to elaborate the impact of race, ethnicity, and socioeconomic status (SES) upon the health of minority populations in the United States. Research sponsored by this announcement will focus on the performance of special studies and analyses of existing data to:

1. Identify the critical features of SES which determine health, delineate the mechanisms and processes whereby social stratification produces disease, and specify the psychological and interpersonal processes that can intensify or mitigate the effects of social structure on health behaviors, access to care, and health outcomes;
2. Explore the need for more accurate descriptions of racial and ethnic status to monitor the differential impact of health policy changes and system reform on minority subpopulations; and,
3. Increase understanding of the impact of ethnicity on health by identifying the ways in which SES, cultural factors, and racial/ethnic variables and discrimination impact on health behaviors, access to health care, and health outcomes.

The "Disadvantaged Minority Health Improvement Act of 1990" (Pub.L. 101-527) which established the Minority Health Statistics Grants Program and subsequent reauthorizing legislation contained in the "Preventive Health Amendments of 1993" (Pub.L. 103-183), recognized the need for improved and refined data to monitor and focus on the differences in health status between and among minority populations.

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 is related to the priority area of Surveillance and Data Systems. (For ordering a copy of "Healthy People 2000," see the section "Where to Obtain Additional Information.")

Authority

This program is authorized under section 306(m) of the Public Health Service Act [42 U.S.C. 242k(m)] as amended.

Smoke-Free Workplace

The 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, 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 nonprofit organizations and institutions, and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, are eligible to apply.

Availability of Funds

Approximately \$500,000 will be available in FY 1995 to fund approximately 3 to 7 awards ranging from \$50,000 to \$200,000. It is expected that the average award will be \$150,000. It is expected that 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 3 years. Funding estimates may vary and are subject to change. Applications requesting funds greater than an upper limit of \$250,000 total costs for any 12-month budget period will be returned to the applicant without review. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

The purpose of this program announcement is to support special studies and analyses that will elucidate the impact of race/ethnicity and SES upon the health of minority populations in the United States.

Research priorities for race/ethnicity and SES have been divided into several categories. Genetics is an important variable; however, it diverts attention from the more influential social and environmental differences which have erroneously been attributed as race differences. Implicit in these priorities are a number of methodological and analytical issues, such as finding and