# UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

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ALLIANCE FOR OPEN SOCIETY INTERNATIONAL, INC. et al.,

Plaintiffs.

05-CV-8209 (VM) (DF)

DECLARATION OF DANIEL E. PELLEGROM

-against-

UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT *et al.*,

Defendants.	

I, DANIEL E. PELLEGROM, hereby declare as follows:

- 1. I am, and have been since 1984, the President of Pathfinder International ("Pathfinder").
- 2. I submit this declaration in support of Pathfinder's motion for a preliminary injunction.

### Pathfinder International

- 3. Pathfinder is a non-profit corporation incorporated under District of Columbia law. It enjoys tax-exempt status under section 501(c)(3) of the Internal Revenue Code. Its primary office is located at 9 Galen Street, Suite 217, Watertown, Massachusetts, 02472-4501.
- 4. Pathfinder was founded in 1957 by Dr. Clarence J. Gamble, a private philanthropist, and it was one of the first U.S.-based organizations to address international population issues. Working in over 20 countries throughout Africa, Latin America, Asia, and the Near East, Pathfinder's mission is to provide access to quality family planning and reproductive health services to women, men, and adolescents

throughout the developing world. In addition to its family planning work, Pathfinder also works to halt the spread of HIV/AIDS, improve maternal and child health, and prevent unsafe abortions. It accomplishes these goals by developing partnerships with local non-governmental organizations, host country governments, the private sector, and health care providers. Pathfinder's Watertown, Massachusetts, office plays a significant role in conceiving of, funding, supervising, evaluating, and otherwise overseeing Pathfinder's international work. Pathfinder's governing philosophy is to provide this assistance with concern for human rights, for the status and role of women, and from the perspective of the clients it serves.

5. Pathfinder's annual budget, which in fiscal year 2005 totaled more than \$76 million, is funded by grants and donations from multiple sources, including Defendants United States Agency for International Development ("USAID") and the United States Centers for Disease Control and Prevention ("CDC"), an operating agency of Defendant Department of Health and Human Services "(DHHS"). Pathfinder also receives funds from several agencies of the United Nations, the Swedish, Canadian, and Dutch governments, the World Bank, and numerous foundations, corporations and individual donors.

## The Global AIDS Act Restrictions

6. Pathfinder carries out a number of programs funded by Defendants
USAID and CDC that are encumbered by restrictions contained in the United States
Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 ("Global AIDS Act").

- 7. The Global AIDS Act contains a "government funds restriction" prohibiting funds made available under the act from being spent on activities that "promote or advocate the legalization or practice of prostitution and sex trafficking," although it allows for the provision of health care and related services to prostitutes. 22 U.S.C. § 7631(e).
- 8. Pathfinder rigorously complies with the government funds restriction and does not challenge it herein.
- 9. The Global AIDS Act also contains a "pledge requirement" providing, in pertinent part, that "no funds made available to carry out this Act . . . may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking." 22 U.S.C. § 7631(f).
- 10. Until this year, USAID did not enforce the pledge requirement against U.S.-based non-governmental grantees such as Pathfinder International. Upon information and belief, CDC and DHHS also did not enforce the pledge requirement against U.S.-based non-governmental grantees for at least some of the period between the enactment of the Global AIDS Act and May 2005.
- Then, in June 2005, USAID applied the pledge requirement to U.S. non-governmental organizations ("US NGOs") by issuing USAID Acquisition & Assistance Policy Directive 05-04 dated June 9, 2005. Neither in this policy directive, nor in any other written document, does USAID either define "explicitly opposing prostitution" or provide clear guidance on what privately funded activities are permissible and impermissible under the pledge requirement.

- 12. Similarly, beginning on or about May 2005, DHHS and CDC began applying the pledge requirement to US NGOs. A copy of a DHHS and CDC Notice titled "Expansion and Support of HIV/AIDS/STI/TB Information, Education, Communication and Behavioral Change Communication Activities in Ethiopia Amendment," 70 Fed. Reg. 29759, 29759-29760 (May 24, 2005), is annexed hereto as Exhibit A.
- 13. DHHS and CDC have not defined the term "explicitly opposing prostitution" nor have they issued guidance to the public explaining which types of activities are permissible and impermissible under this restriction.
- 14. DHHS and CDC have required all recipients of Global AIDS Act funding to "agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization's compliance [with the pledge requirement]." See, e.g., Exhibit A.
- 15. Pathfinder must comply with the pledge requirement as a condition of continuing its USAID-funded programs that include HIV/AIDS components. These programs include a project to improve the quality of health services in Peru and a project to extend service delivery for reproductive health services globally. Pathfinder must also comply with the pledge requirement as a condition of subcontracts it holds with other development organizations to carry out USAID-funded work. These subagreements include programs to improve HIV/AIDS policies in Nigeria, to strengthen community-based programs for HIV/AIDS prevention and treatment in Kenya, to reduce the impact of HIV/AIDS on orphans and vulnerable children in Kenya, to improve services related to HIV prevention, care and treatment in Vietnam, and to develop programs to prevent mother-to-child transmission of HIV in Tanzania.

16. Pathfinder also must comply with the pledge requirement as a condition of continuing its CDC-funded work to implement a program to prevent mother-to-child HIV transmission in Kenya, to scale-up home-based care programs for HIV-positive persons in Tanzania, and to expand psychosocial and peer counseling services in Botswana.

## Pathfinder's Policy

17. Solely in order to comply with the pledge requirement, Pathfinder in July 2005, adopted the following policy:

In order to be eligible for federal funding for HIV/AIDS, Pathfinder opposes prostitution and sex trafficking because of the harm they cause primarily to women. Pathfinder's HIV/AIDS programs seek to promote effective ways to prevent the transmission of HIV/AIDS and to reduce the suffering caused by HIV/AIDS. In order to achieve these goals, Pathfinder works with, and provides assistance and support to and for, many vulnerable groups, including women who are commercial sex workers, who, if not effectively reached by HIV/AIDS programs, will suffer and can become drivers of the HIV/AIDS epidemic.

18. Pathfinder adopted this policy solely in order to remain eligible to receive U.S. government funding to provide desperately needed HIV/AIDS prevention and care work around the world.

### How the Pledge Requirement Harms Pathfinder

- 19. The pledge requirement detrimentally affects Pathfinder and the clients it serves in several ways.
- 20. First, Pathfinder has been forced to stake out a policy position on an issue on which it wished to remain neutral at this time. Were it not for the mandate in the Global AIDS Act, Pathfinder would not have adopted the above policy. As an international development organization operating in multiple countries, each with its own set of laws and cultures, Pathfinder is mindful of the need to refrain from taking policy

positions without careful study and deliberation. With the exception of the antiprostitution policy it adopted to comply with the pledge requirement, Pathfinder's policy positions have been formed only after deeply studying an issue, primarily by examining our own experience promoting access to health care in the developing world.

- 21. Second, Pathfinder has been forced to adopt a policy to comply with a provision that is vague and confusing. Pathfinder believes it is in compliance with the pledge requirement. However, given the lack of guidance from USAID, DHHS and CDC as to the requirement's meaning, it operates in constant fear that defendants USAID, DHHS and CDC will apply an overly broad interpretation of the pledge requirement to Pathfinder's policy and activities and thereby find Pathfinder out of compliance with the pledge requirement.
- 22. Pathfinder is also concerned that the pledge requirement is so vague that Pathfinder is unable to discern which of its activities may run afoul of this restriction.
- 23. I am aware that neither the Global AIDS Act nor any of the Defendants has defined what it means to have a policy "explicitly opposing prostitution," which is required by the pledge requirement. I do not know what they mean by this phrase.
- 24. The third way in which the pledge requirement harms Pathfinder is that Pathfinder engages in a significant amount of activity not funded by the U.S. government that could be barred by an overly broad construction of the pledge requirement's blanket ban on the use of the non-U.S. government funds possessed by Plaintiff Pathfinder to do work that Defendants construe as being insufficiently opposed to sex work. Pathfinder firmly believes that it is complying with the pledge requirement, but it does not know whether defendants USAID, DHHS and CDC agree.

- 25. Much of Pathfinder's HIV/AIDS prevention work is aimed at vulnerable populations, including sex workers. Pathfinder currently runs programs in Ethiopia and India to prevent the spread of HIV among sex workers and has in the past run similar programs in Nigeria and Brazil. Key to these programs are efforts to organize sex workers and to work cooperatively with existing organizations composed of individuals involved in sex work to promote the health, human rights and well-being of sex workers.
- 26. As is common among most international development organizations,
  Pathfinder works with local groups to identify their needs and priorities. Pathfinder seeks
  to assist local groups, including organizations composed of sex workers, in achieving the
  goals they have identified.
- 27. For example, Pathfinder's privately funded Targeted Intervention for Groups at Risk ("TIGRIS") program in India seeks to organize sex workers so that they will collectively agree to engage in HIV prevention methods, such as using condoms. While Pathfinder believes that its organizing of sex workers in India complies with the pledge requirement, it fears that defendants USAID, DHHS and CDC may construe the pledge requirement overly broadly and subject Pathfinder to penalties should sex worker organizations it has fostered or cooperated with then pursue goals that Defendants view as being inconsistent with opposition to prostitution.
- 28. Pathfinder's TIGRIS program also conducts outreach to brothel owners and pimps in an attempt to foster safer sex practices. While Pathfinder conducts this work for the purpose of promoting HIV prevention and assisting the women in the brothels, it also must at times gain the trust of brothel owners in order to gain access to the women it is trying to help. Although Pathfinder believes that this outreach does not

violate the pledge requirement as set forth in the Global AIDS Act, it fears that defendants USAID, DHHS and CDC might view this outreach as being insufficiently "opposed to prostitution."

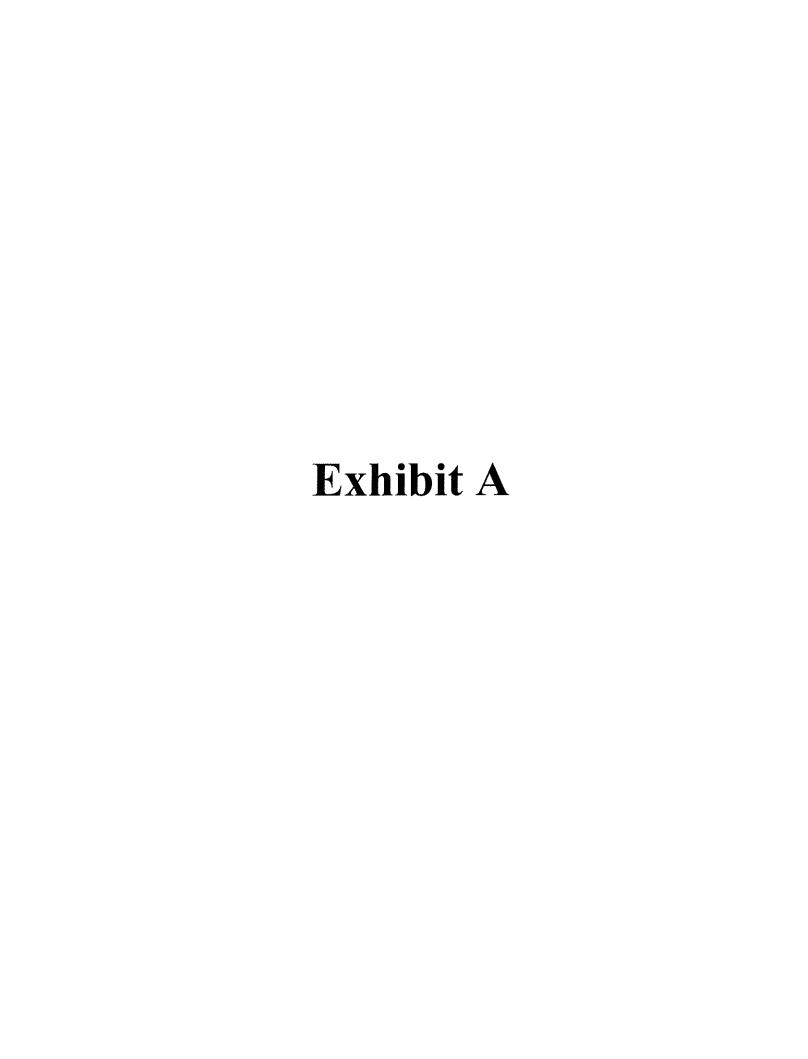
- 29. The fourth way in which the pledge requirement harms Pathfinder concerns Pathfinder's desire to consider resuming work with community organizations in Brazil. Pathfinder has, in the past, worked with local community organizations, which, as part of their efforts to limit exploitation of sex workers, have sought to change regulations surrounding commercial sex work so that they do not serve as a pretext for brothel owners, corrupt police and others to abuse sex workers.
- 30. Pathfinder understands that such activity would likely be construed by defendants USAID, DHHS and CDC as violative of the pledge requirement. Pathfinder is not currently involved in such work. However, were the pledge requirement either lifted or construed in a manner that would allow Pathfinder to resume this important work, Pathfinder would be interested in doing so.
- 31. The fifth way in which the pledge requirement harms Pathfinder is that it affects Pathfinder's active, privately funded advocacy program within the United States, which could be forced to censor itself as a result of the pledge requirement. Part of Pathfinder's mission is to improve the U.S. policy environment for international family planning, reproductive health programs and HIV/AIDS service delivery. Pathfinder accomplishes this by educating U.S. policy-makers and the general public about conditions facing women and their families in developing countries and the impact U.S. policies have on the effectiveness of family planning and HIV/AIDS service delivery. Pathfinder now must ensure that any advocacy it undertakes conforms to the pledge requirement. For example, while Pathfinder may wish to discuss its experience doing

HIV/AIDS prevention work in Brazil, because this program included work with local organizations that advocated to change regulations around sex work, Pathfinder could be barried from freely discussing the lessons of this work.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 7, 2005 Washington, District of Columbia

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#### WORKPLAN TEMPLATE—Continued

Goal							
Objectives	Activities	Measures of effectiveness	Data	Timeframe for assessing progress	Team members responsible		

#### Workplan—Definition of Terms

Goals

Goals are general, "big picture" statements of outcomes a program intends to accomplish to fulfill its mission.

#### Objectives

Objectives are the "big steps" a program will take to attain its goals. Objectives should be S.M.A.R.T. (specific, measurable, achievable, realistic, and time-phased).

#### Activities

Activities are the "smaller steps" a program takes to meet its objectives. Examples include reviewing data and research, identifying resources and staff for program implementation and evaluation, creating Public Service Announcements about screening recommendations, and health provider training about screening technology.

#### Measures of Effectiveness

Measures of effectiveness, or indicators, translate program concepts and expected impacts into specific measures that can be analyzed and interpreted. There should be at least one measure of effectiveness for each objective. The change measured by an indicator should represent progress a program has made toward achieving goals and objectives.

Examples of indicators include: participation rates, individual behavior, health status, and attitude. Success in achieving the goal of maintaining coalition partnerships could be measured by analyzing participation rates or the number of members at the beginning, throughout and near the end of plan implementation. An increase (or decrease/no change) in participation rate indicates level of progress toward meeting the goal.

#### Data

Data is a list of sources that will be used to gather information on measures of effectiveness. Data sources may include: People, observations and documents. Examples of data sources include: Behavioral Risk Factor Surveillance System (BRFSS), Surveillance, Epidemiology, and End Results (SEER), needs and satisfaction assessments, program records and reports, cancer registries, interviews, focus groups, and medical claims data.

#### Attachment D—References for Centers for Disease Control and Prevention RFA AA030, Colorectal Cancer Screening Demonstration Program

1. American Cancer Society. Cancer Facts and Figures, 2005. Atlanta, Georgia:

American Cancer Society, 2005 (publication no. 5008.05).

- 2. Mandel JS, Bond JH, Church TR, Snover DC, Bradley GM, Schuman LM, Ederer F. Reducing mortality from colorectal cancer by screening for fecal occult blood. Minnesota Colon Cancer Control Study. N Engl J Med 1993;328:1365–71.
- 3. Mandel JS, Church TR, Bond JH, et al. The effect of fecal occult-blood screening on the incidence of colorectal cancer. N Engl J Med 2000;343:1603–7.
- Selby JV, Friedman GD, Quesenberry CP Jr, Weiss NS. A case-control study of screening sigmoidoscopy and mortality from colorectal cancer. N Engl J Med 1992; 326:653–657.
- 5. Hardcastle JD, Chamberlain JO, Robinson MH, et al. Randomised controlled trial of faecal-occult-blood screening for colorectal cancer. Lancet 1996; 348:1472– 1477
- 6. Kronborg O, Fenger C, Olsen J, Jorgensen OD, Sondergaard. Randomised study of screening for colorectal cancer with faecal-occult-blood test. Lancet 1996; 348:1467–1471.
- 7. Seeff LG, Nadel MR, Klabunde C, Thompson T, Shapiro JA, Vernon SW, Coates RJ. Patterns and Predictors of Colorectal Gancer Test Use in the Adult U.S. Population. Cancer 2004;100:2093–103.

[FR Doc. 05–10296 Filed 5–23–05; 8:45 am] BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

[Request for Applications (RFA) 05075]

### Expansion and Support of HIV/AIDS/ STI/TB Information, Education, and Communication and Behavioral Change Communication Activities in Ethiopia—Amendment

A notice announcing the availability of fiscal year (FY) 2005 funds for Expansion and Support of HIV/AIDS/STI/TB Information, Education, and Communication and Behavioral Change Communication Activities in Ethiopia was published in the **Federal Register** on Tuesday, May 3, 2005, Volume 70, Number 84, pages 22875–22881. The notice is amended as follows:

Replace the current language, starting in the second column on page 22879 through the first column of page 22880, regarding Prostitution and Related Activities with the following:

Prostitution and Related Activities.
The U.S. Government is opposed to
prostitution and related activities,
which are inherently harmful and
dehumanizing, and contribute to the
phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document ("recipient") cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides. A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any "exempt organizations" (defined as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative or to any United Nations agency).

The following definition applies for purposes of this clause:

• Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

All recipients must insert provisions implementing the applicable parts of

this section, "Prostitution and Related Activities," in all sub-agreements under this award. These provisions must be express terms and conditions of the subagreement, must acknowledge that compliance with this section, "Prostitution and Related Activities," is a prerequisite to receipt and expenditure of U.S. government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization's compliance with this section, "Prostitution and Related Activities."

All prime recipients receiving U.S. Government funds ("prime recipients") in connection with this document must certify compliance prior to actual receipt of such funds in a written statement referencing this document (e.g., "[Prime recipient's name] certifies compliance with the section, 'Prostitution and Related Activities.'") addressed to the agency's grants officer. Such certifications by prime recipients are prerequisites to the payment of any U.S. Government funds in connection with this document.

Recipients' compliance with this section, "Prostitution and Related Activities," is an express term and condition of receiving U.S. government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term. The recipient shall refund to HHS the entire amount furnished in connection with this document in the event it is determined by HHS that the recipient has not complied with this section, "Prostitution and Related Activities."

Dated: May 18, 2005.

#### William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention. [FR Doc. 05–10292 Filed 5–23–05; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Disease Control and Prevention

Health Promotion and Diabetes Prevention Projects for American Indian/Alaska Native (Al/AN) Communities: Adaptations of Practical Community Environmental Indicators

Announcement Type: New. Funding Opportunity Number: RFA AA029.

Catalog of Federal Domestic Assistance Number: 93.945.

Key Dates: Letter of Intent Deadline (LOI): June 23, 2005.

Application Deadline: July 8, 2005.

#### I. Funding Opportunity Description

Authority: Public Health Service (PHS) Act, as amended, sections 317(k)(2), 42 U.S.C. 247b(k)(2).

Background

Type 2 diabetes was rare among American Indians until the 1950s, so uncommon that some scientists believed that indigenous people might have some type of immunity to it. In the past 50 years, diabetes has become one of the most common and serious illnesses among American Indians and Alaska Natives (AI/AN). In 2002, the ageadjusted prevalence of diabetes was 15.3 percent among AI/AN adults, in contrast to seven point three percent for the overall U.S. population (August 1, 2003, MMWR). If not controlled over time, diabetes can damage every organ in the body, diminishing the quality and the length of life. The explanations for high rates of diabetes among indigenous North American peoples, however, are not limited to recent societal trends, environmental changes and deliberate lifestyle choices. They are rooted in historical legacies of forced dispossession of their lands, culture, and language. Understanding and acknowledging the complex array of factors involved in diabetes causation and care are important steps in addressing this disease. Culturallysensitive, community-based prevention interventions, coupled with committed tribal leadership and aggressive clinical programs for risk reduction, are most likely to succeed in stabilizing and eventually reducing the rates of chronic disease in Native communities. Many communities are developing, implementing and evaluating such ecological prevention approaches, which recognize the history, cultural and environmental contributions to high rates of diabetes. These approaches

include multiple individual, family, community, and policy interventions that are expected to have positive impact for current and future generations. Multi-level, broadspectrum approaches to the prevention of diabetes take time to yield results, and can be challenging to sustain the engagement of communities over time.

However, limited practical environmental prevention interventions for diabetes on a community level may have some unique benefits. These benefits may include supplementing multi-level programs by creating an environment supportive of the broader, long-term approaches. Limited practical environmental interventions may also help garner the community's interest in identifying opportunities for environmental adaptations and tracking the progress of community indicators. Incremental progress in improving environmental indicators identified by the community as contributing risk factors for diabetes can have several positive results. For example, they may help to increase community knowledge, confidence in health practices and dispel hopelessness about the devastating impacts of diabetes. Such approaches maintain momentum toward steady progress in identified community health goals and/or health promotion activities.

This program will provide support for community-based and culturally appropriate practical environmental interventions for health promotion and diabetes prevention. These interventions will target practical environmental indicators identified by the community as contributing to risk factors for diabetes. The projects will collaborate with existing local diabetes programs and other community organizations (e.g., schools, supermarkets, restaurants). The interventions will focus on environmental factors that can be adapted and measured by communitylevel indicators. These indicators can reflect behavioral, policy, or practice adaptations by the community and/or its members. The indicators do not involve evaluation of individual behavior or outcomes and do not require human subject approvals.

The prevention interventions proposed (environmental adaptations) to be implemented by the communities can be measured in various ways. For example, by economic means (e.g., purchase rates of foods), environmental (e.g., increased number of walking paths, increased use of fitness facilities, use of pedometers at pow-wows/community dances) or process measures (e.g., school menus meeting nutritional