PHS Actions for Building Capacity in Assurance

Assurance: Guaranteeing the benefits of public health for all. The goal is to ensure that services necessary to achieve agreed-upon goals are provided. The means to accomplish the goal is by encouraging the actions of others, private and public; requiring action through regulation; and by providing funds and other resources, or providing services directly.

Assurance strategy 1: Developing and maintaining the capacity of public health agencies at the State and local levels, and other organizations, to plan, implement, and assure the quality of the services that they provide or need to provide

Office of the Assistant Secretary for Health (OASH)

1. Provide technical assistance to local agencies that receive Adolescent Family Life programs to assure that services provided are of high quality (*Office of Population Affairs*).
1990–91 **1992 and beyond**

2. Continue to provide technical assistance to community-based organizations that receive grants under the Minority HIV/AIDS Education and Prevention Grant Program or the Minority Community Health Coalition Demonstration Grants Program (*Office of Minority Health*).
1990–91 **1992 and beyond**

National Institutes of Health (NIH)

1. Support regional conferences to provide State and local directors with opportunities to share their successes, problems, and concerns in addressing regional problems. Collaborate with State health departments to cosponsor regional conferences and periodic workshops on cardiovascular disease, smoking prevention, and cancer control, and provide for national meetings and workshops of minority health care workers.
1990–91

2. Sponsor periodic State health department workshops to provide updates on critical science and public health issues and offer opportunities to attain capacity building skills for more effective program implementation.
1990–91

3. Involve State and local health officials more directly in programs of basic and applied sciences research. For example, the National Cancer Institute supports a national system linking community-

based oncologists and primary care physicians with NCI-supported cancer centers, clinical cooperative groups, and State health departments.
1990–91

4. Hold national conferences to serve as forums for health care professionals and researchers, such as biennial conferences on high blood pressure and high blood cholesterol.
1992 and beyond

Indian Health Service (IHS)

1. Establish a staff position dedicated to maternal and child health consultation in each IHS area.
1992 and beyond

2. Review maternal and child health programs in each IHS area for quality assurance at least every 2 years by one site visit yearly by the American Academy of Pediatrics, one site visit yearly by the American College of Obstetricians and Gynecologists, two reviews yearly by a qualified contractor, and three to four reviews by headquarters staff.
1992 and beyond

3. The staff of each IHS area will have or be recruiting a maternal and child health consultant.
1992 and beyond

4. Ensure the delivery of high quality services through program research and development.
1992 and beyond

5. Provide policy guidance, technical assistance, and support to the tribes on all aspects of development and implementation of the Community Health Representatives (CHR) Program. Ensure tribal and contractor participation where appropriate and feasible.
1992 and beyond

6. Ensure that tribal program planning is consistent with appropriate provisions of the Indian Self-Determination and Education Assistance Act (P.L. 93-638), and meets appropriate standards of IHS.
1992 and beyond

7. Organize, plan, and develop criteria and implement review of IHS area CHR Programs.
1992 and beyond

8. CHR Program will serve as a primary advisor to the Associate Director (*Office of Health Programs and Special Initiatives Branch*).
1992 and beyond

9. Integrate the revised CHR evaluation methodology into the Resource Requirements Methodology and the Resource Allocation Methodology.
1992 and beyond

10. Prepare a quality assurance IHS Area review document for the CHR.
1992 and beyond

11. Provide the Community Health Aide Practitioner (CHAP) Program with functions currently being performed for the CHR Program.
1992 and beyond

Health Resources and Services Administration (HRSA)

1. Recommend methods for linking primary care medical education to health services delivery. Disseminate recommendations of the March 1990 conference on enhancing care for the underserved (*Office of Planning, Evaluation, and Legislation*).
1990–91

2. Seek input from public health officials who deliver primary care on issues of medical liability, cost of insurance, and other factors that limit access to care (*Bureau of Health Care Delivery and Assistance*).
1990–91

3. Assist in assuring that educational opportunities are accessible to employees in State and local public health agencies. Current State and local health care staffs need additional academic preparation and continued professional training to meet challenges facing the current and future public health system (*Bureau of Health Professions*).
1990–91 **1992 and beyond**

- Encourage more public health personnel involvement in area health education centers, AIDS education and training centers, geriatric education centers, and rural health research centers.

- Ensure online listing of nontraditional public health academic education and continuing professional training options through the computer net-

work of the Public Health Foundation, Association of State and Territorial Health Officials.

• Seek information from public health officials who deliver primary care on the need for continuing education for staff members who assure or deliver such care. Identify special needs for allied health personnel and for facilities appropriate to rural areas.

4. Sponsor a workshop to define and identify facilities that are essential in providing access to health care in rural areas (*Office of Rural Health Policy*).
1990–91

Food and Drug Administration (FDA)

1. Work with sponsors to ensure rapid review of AIDS-related products and encourage sponsors to conduct post-marketing studies.
1990–91

2. Work with sponsors to plan animal tests to generate sufficient information to begin clinical testing of AIDS products in humans within the shortest possible time.
1990–91

3. Work with sponsors to devise clinical testing of AIDS drugs so that sufficient scientific information will result to allow marketing approval.
1990–91

4. Monitor clinical trials for AIDS products to assure the presence of such patient safeguards as informed consent, institutional review board approval, and adverse drug reaction reporting.
1990–91

5. Continue efforts to protect the safety of the nation's supply of blood and blood products. These activities include working with blood and plasma centers to define ways to improve donor education; scientific efforts to improve laboratory screening of donated blood; and increased frequency of routine inspections of blood establishments.
1990–91

6. Continue efforts to encourage the development of vaccines to prevent HIV infection. These efforts include early FDA consultation with product sponsors before animal testing begins and focused regulatory research to add to FDA's capability to assess a vaccine's composition and both the production and laboratory testing methods used.
1990–91

7. Work with blood and plasma centers to define ways to improve donor education and to ensure deferral of those who engage in behaviors that increase the risk of HIV infection.
1990–91

8. Participate in and support PHS activities to reduce the risk of HIV transmission in health care settings. (See assurance strategy 6, FDA item 3.)
1990–91

9. Work with other Federal agencies and health care provider organizations to educate the users of medical devices on their safe and effective use. This includes both barrier devices designed to interrupt the transmission of HIV in health care settings as well as devices with the potential to transmit HIV. (See assurance strategy 6, FDA item 4.)
1990–91

10. Issue "points to consider" and guidelines to monitor and educate manufacturers on ways to produce new biotechnology-derived products safely and expeditiously. Guidelines span the manufacture and testing of biological products.
1990–91

11. Take a proactive approach to ease the entry of biotechnology-based products into the marketplace by facilitating and maintaining contact with manufacturers from the initial developmental stage of the approval process.
1990–91

12. Improve interaction with organizations involved in the manufacture of biotechnology-based products. Provide technical and regulatory support through small-business representatives in the field and support of central activities, such as workshops and information dissemination.
1990–91

13. Initiate a matching-funds agreement with the State of Arkansas for a feasibility study of a national biotechnology cooperative. The study would help define and improve understanding of specific problems encountered by biotechnology companies in bringing their products to market and would design a pilot project to reduce those barriers.
1990–91

14. Continue to emphasize improved food labeling for the consumer, such as the rules that require identification of low fat and low cholesterol foods. Encourage labeling that provides information about the cholesterol and fatty acid content of foods.
1990–91

15. Address the problem of pathogens that may cause serious or fatal infection among those with special risks. Distribute special dietary and food handling advice, either directly or through physicians. (See assessment strategy 1, FDA item 6; assurance strategy 6, FDA item 6.)
1990–91

16. Expedite review of new food additive petitions by providing better guidance to industry on the types of toxicological studies that are required and the standards that these studies must meet.
1990–91

17. Encourage investigational new drug (IND) applications involving treatment, permitting promising drugs still under study to be used by desperately ill patients in life-threatening situations for which no other therapy is available or tolerable.
1990–91

18. Continue to work with FDA staff and drug sponsors to assure that FDA guidelines for the clinical and statistical sections of the New Drug Application achieve their intended effectiveness. These guidelines identify how the agency expects the clinical and statistical data required in the NDA to be analyzed and presented.
1990–91

19. Issue a letter to all New Animal Drug Application holders providing additional interim guidance on how FDA intends to implement the Generic Animal Drug and Patent Term Restoration Act.
1990–91

20. Provide technical assistance and work with industry to develop programs to prevent cross contamination of medicated feed.
1990–91

21. Develop a field program to focus resources and efforts on good practices in veterinary drug use. Develop a concentrated program on cross contamination of animal feeds.
1990–91

22. Work directly with livestock producer organizations, food animal veterinary medical specialty groups, and the U.S. Department of Agriculture to develop and implement farm site quality assurance programs.
1990–91

23. Develop an industry education program to provide a clear understanding of the agency's policies and procedures to the importing community.
1992 and beyond

24. Work to make promising investigational agents available for people with AIDS and HIV-related diseases who have no therapeutic alternatives.
1992 and beyond

25. Continue to inform sponsors of new products for treatment of HIV patients about agency regulatory processes.
1990–91 **1992 and beyond**

26. Expand focused regulatory research to improve the capability to effectively and efficiently assess an HIV vaccine's composition and the production and laboratory testing methods used.
1992 and beyond

27. Complete a comprehensive review of those medical devices on the market that are intended for prevention of HIV transmission, to ensure compliance with standards.
1992 and beyond

28. Implement and evaluate a series of pilot projects, directed toward small biotechnology firms, designed to enhance the regulatory and scientific understanding necessary to bring safe and effective drug and biologic products to the marketplace.
1992 and beyond

29. Issue "points to consider" and guidelines to continue educating manufacturers and sponsors on ways to produce new biotechnology-derived products safely and expeditiously. Guidelines span the manufacture and testing of biological products.

1992 and beyond

30. Distribute to the food biotechnology industry those microbiological criteria and standards that will be used by the agency for the assessment of the safety of food products developed through biotechnology.

1992 and beyond

31. Complete the development of, and make available, guidelines and administrative procedures to facilitate the movement of veterinary biotechnology products to the marketplace. Launch a comprehensive educational initiative directed to the veterinary biotechnology industry. This initiative will stress improved understanding of the regulatory and scientific requisites to successful marketing of safe products.

1992 and beyond

32. Improve communication with small manufacturers of biotechnology-oriented medical devices to enhance their understanding of regulatory requirements, and to share a growing scientific data base about these products as new applications become feasible.

1990–91 **1992 and beyond**

33. Develop and expand an educational initiative on medical foods (foods that are formulated to be administered under medical supervision and are intended for the management of a disease or condition that has distinctive nutritional requirements). This initiative is directed to manufacturers to assure safe manufacturing practices and proper labeling of these foods, and to consumers, to assure their judicious consumption. (See assurance strategy 6, FDA item 13.)

1990–91

34. Encourage foreign governments and producers to assume a greater role in assuring that imported foods meet the requirements of United States statutes.

1992 and beyond

35. Develop and disseminate information for industry concerning the risks associated with migration of materials to food under actual use conditions, and suggest methods for reducing the risk. (See assessment strategy 1, FDA item 8.)

1992 and beyond

36. Develop and disseminate a compendium of guidance for the food industry that reflects the rapid emergence of new food processing technologies. The compendium will include information on the types of toxicological studies that are required and the standards that the studies must meet.

1992 and beyond

37. Continue to work with drug sponsors in designing human testing phase 1 and 2 studies of treatments for life-threatening and severely debilitating illnesses. Strengthen firms' abilities to provide sufficient data for approval without the need for a traditional phase 3.

1992 and beyond

38. Establish a coordinated review and approval process that will effectively address new products involving a drug or device interface. Help industry become more knowledgeable about the process. Submit the required information to comply with the process and expedite the delivery of needed health care products to the marketplace.

1992 and beyond

39. Adopt, on a widespread basis, automated data systems to improve the timeliness and quality of agency review of New Animal Drug Applications. Coordinate this automation initiative to inform industry representatives about the regulatory and technical requirements associated with information submitted as part of this process. (See assessment strategy 2, FDA item 3.)

1992 and beyond

40. Assist the veterinary industry in capitalizing on benefits under provisions of the new Generic Animal Drug and Patent Term Restoration Act.

1992 and beyond

41. Based on the successful experience with pilot State contracts, develop a full scale initiative to curb the illegal sale, distribution, and use of animal drugs at the State level. The program is aimed at surveying drug sales and distribution and use patterns at the State level, and followup, with effective regulatory initiatives, by State authorities. (See assessment strategy 3, FDA item 6.)

1992 and beyond

42. Expand the tissue residue prevention educational initiative directed to the aquaculture industry. Aquaculture producers and producers of feeds for aquaculture species, as well as mariculture, will be emphasized especially in education and voluntary compliance initiatives. The program will be based on an increased scientific understanding of the biology of the various species involved.

1992 and beyond

43. Continue a broad scale farmsite quality assurance program, through coordinated efforts with livestock producer organizations, food animal veterinary medical specialty groups, and the U.S. Department of Agriculture.

1992 and beyond

Centers for Disease Control (CDC)

1. Assist States in developing and implementing assurance plans, including descriptions of specific capacity building activities. Provide technical assistance to States and territories in developing State and local public health capacity building plans.

• Implement technology transfer to State, local, and private laboratories of more efficient and accurate diagnostic testing for specified infectious diseases.

1990–91 **1992 and beyond**

• Provide technical assistance to States and territories to assist them in developing State and local capacity building plans and State Year 2000 Objectives.

1990–91 **1992 and beyond**

• Further strengthen the recruitment, supervision, management, and core training of the Public Health Advisor field staff.

1990–91

• Begin to implement a nationwide, State-based, occupational safety and health intervention program.

1992 and beyond

2. Assist State and local officials in developing the skills and knowledge necessary to carry out assurance for delivery of needed public health services.

• Develop training programs for incorporating state-of-the-art information and techniques into prevention and control programs for infectious diseases.

1990–91 **1992 and beyond**

• Establish and staff a National Laboratory Training Network in seven locations throughout the nation.

1990–91

• Develop a tobacco and health training program for State health departments and assist them in developing tobacco control programs that offer public information activities.

1992 and beyond

• Develop a system to ensure that training programs in injury control are established that enhance the effectiveness of current and new practitioners.

1992 and beyond

• Collaborate with the Health Resources and Services Administration and the Public Health Workforce Consortium to identify the numbers, types, and skills of public health personnel needed in the future to accomplish assurance of public health services.

1992 and beyond

3. Facilitate access by State and Federal agencies to information, technology transfer, and technical assistance or consultation needed to address high priority health problems, such as high infant mortality rates, the need for major interventions in breast and cervical cancer control, and efforts to reduce smoking rates, particularly among women. Ensure that needs and cost-effective methods are identified.

• Provide State health laboratories with data on the quality of their HIV-antibody testing.

1990–91

• Increase local, State, and regional laboratory capacity so that all public health constituents have access to rapid and reliable diagnostic testing for Lyme disease.
1990–91

4. Improve access of State and local health officials to the standards and guidelines necessary to carry out their work.

• Continue to develop guidelines for the protection of health-care workers from communicable disease.
1990–91

• Establish a national reference laboratory network for the measurement of cholesterol to provide an accuracy base to support State and local laboratories in cholesterol measurement.
1992 and beyond

• Develop and distribute standards and guidelines for preventive services for persons with diabetes.
1992 and beyond

5. Monitor and evaluate achievement of process and outcome objectives, and make strategy adjustments when necessary.

• Evaluate demonstration projects on smoking cessation during pregnancy in two States and determine what parts of these projects may be useful in other States.
1990–91

• Provide an external quality assurance program for screening for congenital hypothyroidism, phenylketonuria, and galactosemia.
1990–91

Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)

1. In collaboration with the Office for Substance Abuse Prevention, request applications for support of community-based demonstrations of the synergistic effects of multiple strategies to prevent alcohol abuse in communities, with special emphasis on strategies directed to youth (*National Institute on Alcohol Abuse and Alcoholism*).
1990–91 **1992 and beyond**

2. Publish and disseminate data from research demonstration projects to evaluate effectiveness of treatments for homeless persons with alcohol and other drug problems (*National Institute on Alcohol Abuse and Alcoholism*).
1990–91 **1992 and beyond**

3. Monitor and direct a large-scale multisite clinical trial of specially matched patients with treatments. (*National Institute on Alcohol Abuse and Alcoholism*).
1990–91 **1992 and beyond**

4. In collaboration with the Office of Treatment Improvement, establish and evaluate a drug abuse diagnostic unit in the District of Columbia, making 300 outpatient slots and 80 residential slots available to the District (*National Institute on Drug Abuse*).
1990–91

5. Serve as an informational resource, providing publications, technical assistance, and replicating clinics at other sites at the request of States or territories (*National Institute on Drug Abuse*).
1992 and beyond

6. In collaboration with the Health Resources and Services Administration, award and evaluate 21 grants for the integration of primary health care with drug abuse services; identify through services research what resources are required to meet national, treatment, or prevention goals; and make recommendations to the Administration, States, and Congress (*National Institute on Drug Abuse*).
1990–91 **1992 and beyond**

7. Provide funding and technical assistance to State mental health agencies for the demonstration and evaluation of community support and rehabilitation services affecting the elderly mentally ill, the homeless mentally ill, mentally ill young adults with substance abuse problems (*National Institute of Mental Health*).
1990–91

8. Review all State- and U.S.-related jurisdiction plans for the development of community-based mental health services, as required by P.L. 99-660, and provide technical assistance for implementing these plans (*National Institute of Mental Health*).
1990–91

9. Include evaluation components in each State-level grant under the Child and Adolescent Service System Program (CASSP) to evaluate their impact on public mental health policies for emo-

tionally disturbed children and adolescents. Develop a technical assistance capacity to aid new CASSP grantees in the development of better policy evaluation methodology (*National Institute of Mental Health*).
1990–91

10. Award additional Mental Health Statistics Improvement Program capacity development grants (*National Institute of Mental Health*).
1992 and beyond

11. Conduct a second workshop for State mental health staff on evaluation and research strategies and program assessment tools (*National Institute of Mental Health*).
1992 and beyond

12. Convene a meeting of State mental health authorities to analyze findings from the McKinney Mental Health Services for the Homeless Block Grant demonstration projects relevant to planning, implementing, and evaluating Statewide services for the homeless mentally ill (*National Institute of Mental Health*).
1992 and beyond

13. Develop a series of training workshops on developing and administering mental health services to minorities in coordination with the Health Resources and Services Administration, and State and County Mental Health Services (*National Institute of Mental Health*).
1992 and beyond

14. Direct projects to assure local, State, and Federal models for effective service and service system approaches to prevention, treatment, and rehabilitative services for high risk youth (*Office for Substance Abuse Prevention*).
1990–91

15. Create a well-constructed evaluation plan for all OSAP-funded projects to measure the effectiveness of their interventions (*Office for Substance Abuse Prevention*).
1990–91

16. Develop an evaluation plan to include cross-site evaluation studies of selected high-risk youth grant programs (*Office for Substance Abuse Prevention*).
1990–91

17. Initiate contract planning for an evaluation of pregnancy and post partum programs (*Office for Substance Abuse Prevention*).
1990–91

18. In collaboration with the States, develop guidelines for State drug abuse plans (*Office for Treatment Improvement*).
1990–91

19. Provide technical assistance to the States to support their administration of services under the block grants (*Office for Treatment Improvement*).
1990–91

Agency for Toxic Substances and Disease Registry (ATSDR)

1. Continue with cooperative agreements with States for the purpose of capacity building at the State and local level. Current relationships are designed to build capacity for conducting health assessments, conducting site-related pilot health studies, training health professionals in toxic-exposure patient management, responding to unscheduled releases of toxic substances, and for equipping poison control centers to provide consultations on hazardous substance problems.
1990–91 **1992 and beyond**

2. Expand the capabilities of primary care physicians and emergency room personnel for responding to toxic substance exposure. Use such organizations as the National Association of County Health Officials and the Association of State and Territorial Health Officials for this transfer of technology.
1992 and beyond

Agency for Health Care Policy and Research (AHCPR)

Continue to disseminate, through the User Liaison Program, new and relevant findings to State and local governments. Continue to work with the Health Resources and Services Administration to disseminate information through area health education centers and geriatric education centers, and to address rural health issues through rural health services centers.
1990–91 **1992 and beyond**