

leave your name, address, and telephone number and instructed to identify the announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance can be obtained from: William Paradies, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341-4146, Telephone (770) 488-2721, Internet address: wep2@cdc.gov

General program assistance can be obtained from: Joseph B. Smith, Disability and Health Branch, National Center for Environmental Health, CDC, 4770 Buford Highway, Building 101, Mailstop F-29, Atlanta, Georgia 30341, Telephone (770) 488-7082, Internet address: jos4@cdc.gov

Research-related technical assistance for Focus Areas 1 and 2 is available from: John F. Hough, Dr.P.H., National Center for Environmental Health, CDC, 4770 Buford Highway, Building 101, Mailstop F-29, Atlanta, Georgia 30341, Telephone (770) 488-7830, Internet Address: jph7@cdc.gov

Research-related technical assistance for Focus Area 3 is available from: Donald J. Lollar, Ed.D., National Center for Environmental Health, CDC, 4770 Buford Highway, Building 101, Mailstop F-29, Atlanta, Georgia 30341, Telephone (770) 488-7094, Internet address: dcl5@cdc.gov

Dated: April 11, 2000.

John L. Williams,

Director, Procurement and Grants Office.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. 93631-00-02]

Developmental Disabilities: Request for Public Comments on Proposed Developmental Disabilities Funding Priorities for Projects of National Significance for Fiscal Year 2000

AGENCY: Administration on Developmental Disabilities (ADD), ACF, DHHS.

ACTION: Notice of request for public comments on developmental disabilities tentative funding priorities for Projects of National Significance for Fiscal Year 2000.

SUMMARY: The Administration on Developmental Disabilities (ADD) announced that public comments are being requested on tentative funding priorities for Fiscal Year 2000 Projects of National Significance prior to being announced in its final form.

We welcome comments and suggestions on this proposed announcement and funding priorities that will assist in bringing about the increased independence, productivity, integration, and inclusion into the community of individuals with developmental disabilities.]

DATES: The closing date for submission of comments is June 19, 2000.

ADDRESSES: Comments should be sent to: Sue Swenson, Commissioner, Administration on Developmental Disabilities, Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade, SW, Room 300F, Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Administration for Children and Families (ACF), Pat Laird, 370 L'Enfant Promenade, SW, Room 300F, Washington, DC, 20447, 202/690-7447.

SUPPLEMENTARY INFORMATION: This announcement consists of two parts:

Part I

Background

A. Goals of the Administration on Developmental Disabilities

The Administration on Developmental Disabilities is located within the Administration for Children and Families, Department of Health and Human Services (DHHS). Although different from the other ACF program administrators in the specific constituency it serves, ADD shares a common set of goals that promote the economic and social well being of families, children, individuals and communities. Through national leadership, we see:

- Families and individuals empowered to increase their own economic independence and productivity;
- Strong, health, supportive communities having a positive impact on the quality of life and the development of children;
- Partnerships with individuals, front-line service providers, communities, States and Congress that enable solutions which transcend traditional agency boundaries;
- Services planned and integrated to improve client access; and
- A strong commitment to work with Native Americans, individuals with

developmental disabilities, refugees and migrants to address their needs, strengths and abilities.

Emphasis on these goals and progress toward them will help more individuals, including those with developmental disabilities, to live productive and independent lives integrated into their communities. The Projects of National Significance Program is one means through which ADD promotes the achievement to these goals.

Two issues are of particular concern with these projects. First, there is a pressing need for networking and cooperation among specialized and categorical programs, particularly at the service delivery level, to ensure continuation of coordinated services to people with development disabilities. Second, project findings and successful innovative models of projects need to be made available nationally to policy makers as well as to direct service providers.

B. Purpose of the Administration on Developmental Disabilities

The Administration on Developmental Disabilities is the lead agency within ACF and DHHS responsible for planning and administering programs that promote the self-sufficiency and protect the rights of individuals with developmental disabilities.

The 1996 Amendment (Public Law 104-183) to the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6000 *et seq.*) (the Act) supports and provides assistance to States and public and private nonprofit agencies and organizations to assure that individuals with developmental disabilities and their families participate in the design of and have access to culturally competent services, supports, and other assistance and opportunities that promote independence, productivity and integration and inclusion into the community.

The Act points out that:

- Disability is a natural part of the human experience that does not diminish the right of individuals with developmental disabilities to enjoy the opportunity for independence, productivity and inclusion into the community;
- Individuals whose disabilities occur during their development period frequently have severe disabilities that are likely to continue indefinitely;
- Individual with developmental disabilities often require lifelong specialized services and assistance, provided in a coordinated and culturally competent manner by many

agencies, professionals, advocates, community representatives, and others to eliminate barriers and to meet the needs of such individuals and their families;

The Act further finds that:

- Individual with developmental disabilities, including those with the most severe developmental disabilities, are capable of achieving independence, productivity, and integration and inclusion into the community, and often require the provision of services, supports and other assistance to achieve such;

- Individual with developmental disabilities have competencies, capabilities and personal goals that should be recognized, supported, and encouraged, and any assistance to such individuals should be provided in an individualized manner, consistent with the unique strengths, resources, priorities, concerns, abilities, and capabilities of the individual;

- Individuals with developmental disabilities and their families are the primary decision makers regarding the services and supports such individuals and their families receive; and play decision making roles in policies and program that affect the lives of such individuals and their families; and

- It is the nation's interest for individuals with developmental disabilities to be employed, and to live conventional and independent lives as a part of families and communities.

- Toward these ends, ADD seeks to enhance the capabilities of families in assisting individuals with developmental disabilities to achieve their maximum potential, to support the increasing ability of individuals with developmental disabilities to exercise greater choice and self-determination, to engage in leadership activities in their communities, as well as to ensure the protection of their legal and human rights.

- Programs funded under the Act are:
 - Federal assistance to State developmental disabilities councils;

- State system for the protection and advocacy of individual's rights;

- Grants to university affiliated programs for interdisciplinary training, exemplary services, technical assistance, and information dissemination; and

- Grants for Projects of National Significance.

C. Description of Projects of National Significance

Under Part E of the Act, demonstration grants and contracts are awarded for projects of national significance that support the

development of national and State policy to enhance the independence, productivity, and integration and inclusion of individuals with developmental disabilities through:

- Data collection and analysis;
- Technical assistance to enhance the quality of State developmental disabilities councils, protection and advocacy systems, and university affiliated programs; and
- Other projects of sufficient size and scope that hold promise to expand or improve opportunities for individuals with developmental disabilities, including:

- technical assistance for the development of information and referral systems;
- educating policy makers;
- Federal interagency initiatives;
- the enhancement of participation of racial and ethnic minorities in public and private sector initiatives in developmental disabilities;
- transition of youth with developmental disabilities from school to adult life.

Section 162(d) of the Act requires that ADD publish in the **Federal Register** proposed priorities for grants and contracts to carry out Projects of National Significance. The Act also requires a period of 60 days for public comment concerning such proposed priorities. After analyzing and considering such comments, ADD must publish in the **Federal Register** final priorities for such grants and contracts, and solicit applications for funding based on the final priorities selected.

The following section presents the proposed priority areas for Fiscal Year 2000 Projects of National Significance. We welcome specific comments and suggestions. We would also like to receive suggestions on topics which are timely and relate to specific needs in the developmental disabilities field.

Please be aware that the development of the final funding priority is based on the public comment response to this notice, current agency and Departmental priorities, needs in the field of developmental disabilities and the developmental disabilities network, etc., as well as the availability of funds for this fiscal year.

Part II

Fiscal Year 2000 Proposed Priority Areas for Projects of National Significance

ADD is interested in all comments and recommendations which address areas of existing or evolving national significance related to the field of developmental disabilities.

ADD also solicits recommendations for project activities which will advocate for public policy change and community acceptance of all individuals with developmental disabilities and families so that such individuals receive the culturally competent services, supports, and other assistance and opportunities necessary to enable them to achieve their maximum potential through increased independence, productivity, and integration into the community.

ADD is also interested in activities which promote the inclusion of all individuals with development disabilities, including individuals with the most severe disabilities, in community life; which promote the interdependent activity of people with developmental disabilities and people without disabilities; and which recognize the contributions of these people (whether they have a disability or not), who share their talents at home, school, and work, and in recreation and leisure time.

No proposals, concept papers or other forms of applications should be submitted at this time. Any such submission will be discarded.

ADD will not respond to individual comment letters. However, all comments will be considered in preparing the final funding solicitation announcement and will be acknowledged and addressed in that announcement.

Please be reminded that, because of possible funding limitations, the proposed priority areas listed below may not be published in a final funding solicitation for this fiscal year.

Comments should be addressed to: Sue Swenson, Commissioner, Administration on Developmental Disabilities, Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade, SW, Room 300F, Washington, DC 20447.

Proposed Fiscal Year 2000 Priority Area 1: Mobilizing for Change/Rapid Deployment of Good Ideas

In March of 1993, President Clinton unveiled his new initiative to reinvent the federal government. He proposed a leaner, more efficient government that viewed the American people as its customers. The President discussed how all of us to some extent count on the government to do certain things such as, "protect the environment, to provide education and health care and other basic needs." However, he pointed out that a "democracy can become quickly an empty phrase, if those who are elected to serve cannot meet the needs

of the people except with Government that costs too much or is too slow or too arrogant or too unresponsive." Federal workers were empowered to reinvent their agencies in ways that would put customers first, cut red tape, get results, and get back to basics.

At ADD, our agency efforts resulted in a document called "The Roadmap to the Future," which was developed together with the programs it funds, establishes a course of action for ADD and for its programs. The Roadmap defines the mission and vision of ADD, of the State Developmental Disabilities Councils (DDCs), of the Protection and Advocacy Systems (P&As), of the Universities Affiliated Programs (UAPs), and of the Projects of National Significance (PNS), and it identifies goals created to increase the independence, productivity, and integration and inclusion of people with developmental disabilities and their families. Program activities will be directed toward achieving the Roadmap goals.

The Projects of National Significant (PNS) Program is one of the activities of ADD. Every year since 1975 there have been model demonstration projects funded to increase the independence, productivity, and integration and inclusion of people with developmental disabilities. These projects have generated inventive approaches, strategies, and methodologies in addressing pervasive problems or needs of individuals with developmental disabilities and their families. Over the years, PNS projects have contributed to the knowledge base of the developmental disabilities field and the larger disability field as well. In the past decade, the leadership capacity of individuals with developmental disabilities, especially self-advocates, has been nourished and strengthened by the funding of PNS projects.

Although dissemination of information from these projects has been a requirement of funding, it is a concern of ADD's that the rich volume of knowledge and information produced by these projects has not reached a broader of people who either could directly benefit from it or are in a position to replicate it. More important, depending on the target audience, we have not been successful in influencing permanent behavioral changes. The explosion of communications arts and technology offer new possibilities for reaching a broader audience. A major challenge lies in connecting with those segments of our population who do not have easy access to a computer or English is not their primary language or there are cultural differences. New design models of transferring knowledge

and fostering utilization must be explored if we are to meet the needs of Americans with disabilities and their families. ADD is extremely interested in supporting this "reinvention" of new models under this priority area.

These models must surpass our standard methods of communication best practices and practical solutions to those we serve and those who serve them. Projects must be outcome driven—demonstrating effectiveness and behavioral changes of the targeted population. Content area is open to any proven, positive results-based practice, methodology or processing the field of developmental or other disabilities or directly related field such as universal design. It can be an expansive as systems change or a new paradigm. These new models should consider creative partnering implementing the project. A few examples of this by the Federal government are the JedI project under the U.S. Geological Survey and The Knowledge Loom under the U.S. Department of Education/Office of Educational Research and Improvement. The former, which stands for joint education initiative, utilized CD-ROM technology containing different types of data and in conjunction with teachers developed educational materials that could be used in the classroom. The latter is a recent project funded to create an electronic interactive workspace for anyone interested in the education environment.

In the last century we were the beneficiaries of extraordinary human developments that would have been considered inconceivable by many; it has raised our level of expectation for this new century. This is no less true for people with developmental disabilities and their families who, in this age of the Internet, the PC, and satellite downlinks, expect there will be new models available to everyone who needs them. ADD views this priority area as an unprecedented opportunity to take what we have learned through federally funded projects and find enterprising, inventive, and imaginative ways of using the knowledge so that all will benefit—people with developmental disabilities and other disabilities, professionals who serve them, their families, and the communities in which they live.

Proposed Fiscal Year 2000 Priority Area 2: Bridging the Digital Divide: Building Content

In a White House speech on February 2, 2000, President Clinton stated: "Access to computers and the Internet and the ability to effectively use this technology are becoming increasingly

important for full participation in America's economic, political and social life. People are using the Internet to find lower prices for goods and services, work from home or start their own business, acquire new skills using distance learning, and make better informed decisions about their healthcare needs."

The President expressed his concern over the widening gap of access: "Access to computers and the Internet has exploded during the Clinton-Gore Administration. Unfortunately, there is strong evidence of a 'digital divide'—a gap between those individuals and communities that have access to these Information Age tools and those who don't. In some instances, this divide is actually widening." The President has proposed three basic approaches to narrowing the digital divide: (1) Provide hardware and connections to people who do not yet have them; (2) provide training in the use of computers and the internet; and (3) build relevant content on the Internet, to attract new users. ADD continues to encourage its grantees and partners in all three of these strategies, but realizes that a national approach is necessary to the third strategy of building relevant content.

A person with a developmental disability is legislatively defined as someone whose disability occurred before age 22; is severe and lifelong; and is likely to result in an ongoing, long-term need for services and supports. In other words, people with developmental disabilities are likely to need to rely on multiple systems of supports in order simply to live their lives. And yet, information that could be used to improve decision-making is not easily accessible to people with developmental disabilities, their families, their advocates, their providers of services and supports, or even to the policymakers who design and fund systems. For people with developmental disabilities, Internet access to relevant information is limited.

For the majority of people with developmental disabilities and their families, Medicaid is the most relevant system; it is their lifeline. Yet it is a very complex system whose possibilities change almost constantly, and quite rapidly. As States submit new ideas to the Health Care Finance Administration (HCFA) in Home and Community-Based Services (HCBS) waiver plans, and as these state-generated plans are approved, possibilities for all other States and all other citizens shift. In addition, the Medicaid program is complex due to the "patchwork quilt of incremental statutory amendments and

administrative policy changes spread over several decades.” (GAO, 1996)

Nevertheless, many (though not all) of the Medicaid questions to which people need answers are repetitive and sometimes simple. Clear, honest, user-friendly answers to frequently asked questions are often a feature of Web sites on any topic and may be one of the best uses of the Internet.

ADD is proposing to fund one project to build an Internet site that will provide relevant content and attractive information on what is possible under the Medicaid program. The site should be user-friendly and useful to a broad range of users, including people with developmental and other related disabilities, their families, their advocates, DD network members, state policymakers, regional HCFA staff, and other interested persons. The site should be responsive to the needs and wants of its users, and should collect and measure user satisfaction. It should post frequently asked questions (FAQs) about Medicaid with their answers, and should encourage frank and open “human” interchanges between users. The site must be accessible to people with a broad range of disabilities. Proposing organizations must show that they (1) are credible sources of information to people with developmental disabilities and (2) that they intend to comply with accessibility standards and go beyond compliance to improve access as much as possible. Special care should be taken to make the site useful and attractive to young persons with developmental and other disabilities.

Proposed Fiscal Year 2000 Priority Area 3: Managing Our Program Knowledge Through Web Improvement

The Developmental Disabilities Assistance and Bill of Rights Act (DD Act) provides authorization for three State Programs and a national program that seek to increase the independence, productivity, and inclusion of persons with developmental disabilities.

A Developmental Disabilities Council (DD Council) in each State promotes, through systemic change, capacity building, and advocacy activities, the development of a comprehensive consumer-centered system of coordinated and culturally competent services, supports, and other assistance. The priority areas addressed by DD Councils include employment, community living, child development, and system coordination and community education.

The Protection and Advocacy (P&A) System provides for the protection and advocacy of legal and human rights. The

P&A System advocate on behalf of, and provide advocacy services to persons with developmental disabilities in issue areas related to their disabilities, including: education, abuse and neglect, institutional and habitation services, guardianship issues, and housing issues.

The University Affiliated Program (UAPs) are public and private non-profit agencies in the States and territories, each affiliated with a university. Each UAP receives annual discretionary funding for operational and administrative support, which provides a platform for interdisciplinary training, clinical and community-based service activities, technical assistance to community services personnel, and information/dissemination activities.

In addition to State-based programs, ADD funds research and demonstration grants in an effort to address and increase our understanding of issues of national scope. The Projects of National Significance (PNS) program focuses on the most pressing issues affecting people with developmental disabilities and their families. Project issues transcend the borders of States and territories, while project designs are oriented to permit local implementation of practical solutions.

Each of these programs has a uniqueness and breadth of knowledge that if managed through modern technology would result in a knowledge resource warehouse. The nation cannot afford a digital divide between these programs and between these programs and those they serve. With these programs in mind, ADD is interested in funding a project for the development or enhancement of a model website whose design features are easily employable by each program; its approach on the cutting edge. It should be seen as the beginning of a new form of cyber architecture with a focus on continuous improvement that will enable those programs to improve their use of the web and their ability to hyperlink to others.

This new model website would enhance the ability of ADD’s programs to exchange information and build upon ongoing diverse enterprises throughout the developmental disabilities community. At the same time, the contributions and achievements of these programs towards the quality of life of persons with disabilities and their families should be easily disseminated and accessible. It should support the development of strategies, technologies, and media channels for the management of knowledge generated/produced by these programs. This site should operate as an information center as well as a networking tool for the programs and

others. This website is not about outcomes exclusively but content and access to content that affects the lives of people with developmental disabilities and their families. ADD envisions that the first year would begin with the UAPs and the PNS projects with the understanding the model website be inclusive of the other programs over the duration of the project. It is expected that the site would be open to everyone; including the average citizen, people working in each program, and people working in related programs. Also, it should be accessible to people with a broad range of disabilities utilizing the most current accessibility standards. ADD would be supportive of applicants that represent a consortia of UAPs and DD Councils.

(Federal Catalog of Domestic Assistance Number 93.631—Developmental Disabilities—Projects of National Significance)

Dated: April 7, 2000.

Sue Swenson,

Commissioner, Administration on Developmental Disabilities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4202]

Agency Information Collection Activities; Announcement of OMB Approval; Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 2, 2000 (65 FR 4979), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An