

participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the: European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Impurities: Residual Solvents

In the **Federal Register** of October 12, 1999 (64 FR 55296), FDA published the notice of availability of the draft guidance entitled "Impurities: Residual Solvents" (VICH GL18) giving interested persons until November 12, 1999, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 14 through 16, 2000, the VICH Steering

Committee endorsed the final guidance for industry, VICH GL18.

This guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in the final guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food-producing animals. The guidance is intended to assist in developing new animal drug applications (referred to as marketing applications in the final guidance) submitted to the European Union, Japan, and the United States.

This final level 1 guidance is being issued consistent with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations. Information collected is covered under OMB control number 0910-0032.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cvm>.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written or electronic comments regarding this guidance. Written comments should be submitted to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Comments may also be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select "99D-4071 Impurities: Residual Solvents in New

Veterinary Medicinal Products" and follow the directions.

Dated: May 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2125-N]

Medicaid Program; Infrastructure Grant Program To Support the Design and Delivery of Long Term Services and Supports That Permit People of Any Age Who Have a Disability or Long-Term Illness To Live in the Community

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of funding availability.

SUMMARY: This notice announces the availability of approximately \$70 million in grant funding through "Systems Change Grants for Community Living". The "Systems Change" grants include four distinct competitive grant opportunities: (1) "Nursing Facility Transitions"; (2) "Community-Integrated Personal Assistance Services and Supports"; (3) "Real Choice Systems Change"; and (4) "National Technical Assistance Exchange for Community Living". The four grants are designed to assist States to develop enduring infrastructures that support people of any age who have a disability or long-term illness to live and participate in their communities. Applicants include States, State instrumentalities, and other eligible entities as further described in the notice. This notice also contains information about the application process.

DATES: *Deadline for Letter of Intent To Apply:* Applicants should submit a letter of intent to apply for a grant no later than June 8, 2001. Although it is not mandatory for an applicant to submit a letter of intent, we would appreciate receiving a letter of intent from each applicant because it will help us to plan our review panels.

Deadlines for Submission of Grant Applications: To be considered under the Fiscal Year 2001 funding cycle, grant applications must be submitted by the deadlines listed below:

Grants	Application deadline
<ul style="list-style-type: none"> Nursing Facility Transitions <ul style="list-style-type: none"> Independent Living Partnerships State Program Grants Community-integrated Personal Assistance Services and Supports Real Choice Systems Change National Technical Assistance Exchange for Community Living 	<p>July 20, 2001.</p> <p>July 20, 2001.</p> <p>July 20, 2001.</p> <p>July 16, 2001.</p>

ADDRESSES: Letter of Intent to Apply:

The letter of intent to apply is included in the solicitation as Appendix Seven "Letter of Intent to Apply"; the solicitation may be found on the HCFA web site at: <http://www.hcfa.gov/medicaid/systemschange>. All letters of intent to apply must be submitted to: Jeremy Silanskis, Health Care Financing Administration, Center for Medicaid and State Operations, DEHPG/DASI, Mail Stop: S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850. Letters of intent to apply may be submitted by facsimile to Jeremy Silanskis at (410) 786-9004. For those unable to access the HCFA web site containing the full solicitation (including Appendices), copies of the solicitation are available through Susan Hill. (See **FOR FURTHER INFORMATION CONTACT.**)

Application Materials: Standard application forms and related instructions are available through either: (1) Judith Norris, Health Care Financing Administration, Office of Internal Customer Support, AGG, Grants Management Staff, Mail Stop: C2-21-15, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, (410) 786-5130, Internet:jnorris1@hcfa.gov, or (2) the HCFA web site at: <http://www.hcfa.gov/ord/grantop.htm>.

Submission of Application: Applicants are required to submit (1) an original and two copies of the application and (2) a 3¼" floppy disk containing at least the narrative and the budget. Although it is not mandatory and does not impact on the scoring of an application, we would appreciate receiving an original and 14 copies of the application. For further information regarding the provisions of the grants, application format and requirements, review criteria and procedures, explanation of timely submission, and other relevant information, applicants must refer to the grant solicitation available on the HCFA web site at: <http://www.hcfa.gov/medicaid/systemschange>.

All application forms and related materials must be submitted to: Judith Norris, Health Care Financing Administration, Office of Internal Customer Support, AGG, Grants

Management Staff, Mail Stop: C2-21-15, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, (410) 786-5130, Internet:jnorris1@hcfa.gov.

Each type of grant has a specific closing date. (See **DATES** section above.) Applications mailed through the U.S. Postal Service or a commercial delivery service will be considered "on time" if received by close of business on the closing date, or postmarked (first class mail) by the date specified and received within five business days. If express, certified, or registered mail is used, the applicant should obtain a legible dated mailing receipt from the U.S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailings. Applications that do not meet the above criteria will be considered late applications. Applicants who submit late applications will be notified that their applications were not considered in the competition. Late applications will not be reviewed and will be returned to the applicant.

Web Site: To obtain up-to-date information about the "Systems Change" grants and a complete grant solicitation, please check our web site at: <http://www.hcfa.gov/medicaid/systemschange>. For those unable to access the HCFA web site containing the full solicitation (including Appendices), copies of the solicitation are available through Susan Hill. (See **FOR FURTHER INFORMATION CONTACT.**)

FOR FURTHER INFORMATION CONTACT:

Questions about the grant program may be directed to: Susan Hill, Health Care Financing Administration, Center for Medicaid and State Operations, DEHPG/DASI, Mail Stop: S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, (410) 786-2754, Internet:shill@hcfa.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

People of all ages who have a disability or long-term illness generally express the same desire to live in the community as do most other Americans. They express a desire to live in their own homes, make their own decisions about daily activities, work, learn, and maintain important social relationships. They express a desire to contribute and

participate in their communities and family life.

In 1990, the Congress enacted the Americans with Disabilities Act (ADA) (Pub. L. 101-336). The ADA recognized that "society has tended to isolate and segregate individuals with disabilities, and, despite some improvements, such forms of discrimination against individuals with disabilities continue to be a serious and pervasive social problem" (42 U.S.C. section 12101(a)(2)). The ADA gave legal expression to the desires and rights of Americans to lead lives as valued members of their own communities despite the presence of disability.

Over the past few years, a consensus for assertive new steps to improve the capacity of our long-term support systems to respond to the desires of our citizenry has been building. Federal, State, and local governments have begun to take actions to renew and reaffirm a commitment to improving the systems that will support people of all ages with disabilities or long-term illnesses who wish to live in their communities.

Several Federal and State initiatives are underway to make community living a reality for more people. We adopted a number of Medicaid policy reforms and issued grants to facilitate State efforts to improve their community services systems. Numerous States have implemented home and community-based waivers through the Medicaid program. As States learn more from these experiences, waivers will continue to evolve. States are interested in building in more consumer choice and consumer-directed services. In addition, the Substance Abuse and Mental Health Services Administration (SAMHSA) announced planning grants to assist States in their planning efforts. The U.S. Department of Housing and Urban Development (HUD) entered into a memorandum of understanding with HHS to coordinate community housing subsidies with human service funds in a manner that will make transition from nursing facilities to the community more feasible. The Administration on Aging (AoA) inaugurated a nationwide caregiver support program.

The Congress also recognized that States face formidable challenges in their efforts to fulfill their legal responsibilities under the ADA. The Congress appropriated funds for these "Systems Change" grants specifically to improve community-integrated services.

In February 2001, President George W. Bush announced a broad "New Freedom Initiative" to "tear down barriers to equality" and grant a "New Freedom" to children and adults of all ages who have a disability or long term illness so that they may live and prosper in their communities. For more information on the President's "New Freedom Initiative", please visit the web site at: <http://www.whitehouse.gov>.

The "Systems Change Grants for Community Living" described in this document represent an expression of support for States' efforts to provide additional or improved support for community living. In addition, these grants support: the President's "New Freedom Initiative"; the States' efforts to fulfill the ADA; and the long-standing desire of people of all ages who have a disability or long-term illness to live and participate in their communities with dignity and value.

II. Overview and General Requirements for All "Systems Change" Grants

Attached is a chart summarizing the Systems Change Grants. The following four distinct competitive grant solicitations comprise the "Systems Change" grants:

- *"Nursing Facility Transitions (TRANSITIONS)" grants:* The purpose of the "TRANSITIONS" grants is to help eligible individuals make the transition from nursing facilities to the community. Between \$10 to \$14 million in two types of grants are available from HCFA: State Program grants and Independent Living Partnership grants. State Program grants can be used for a wide range of activities, for example, a State may wish to use State Program grant funds to develop strategies for linking individuals with disabilities to Section 8 rental housing vouchers or developing other coordinated housing strategies. The Independent Living Partnership grants are designed to promote partnerships between States and selected Independent Living Centers (ILCs) ¹ to support the transition of individuals from nursing facilities to their communities.

- *"Community-Integrated Personal Assistance Services and Supports (Community PASS)" grants:* Personal assistance is the most frequently used

service that enables people with a disability or long-term illness to live in the community. Many States have taken a leadership role in designing systems that not only offer the basic personal assistance service, but also make that service available in a manner that affords consumers maximum control over the selection of individuals working on their behalf and the manner in which services are provided. These grant funds will be used by States to improve personal assistance services that are consumer-directed or offer maximum individual control. Grants totaling \$5 to \$8 million are available to support States' efforts to improve community-integrated personal assistance services for children and adults of any age who have a disability or long-term illness.

- *"Real Choice Systems Change (Real Choice)" grants:* The goal of these grants is to help design and implement effective and enduring improvements in community long-term support systems to enable children and adults of any age who have a disability or long-term illness to live and participate in their communities. Direct grants totaling \$41 to \$43 million are available to assist States and their disability and aging communities to work together to find viable ways to expand or improve the design and delivery of community-integrated services. The funds will also support the public-private partnerships and broad public participation (including a consumer task force) that are generally needed to accomplish such an ambitious undertaking.

- *"National Technical Assistance Exchange for Community Living (The Exchange)" grant:* This national technical assistance grant will support the "Real Choice Systems Change" grants, the "Nursing Facility Transitions," and the "Community-Integrated Personal Assistance Services and Supports" efforts. The purpose of this national technical assistance initiative will be to provide technical assistance, training, and information to States, Grantees, consumers, families, and other agencies and organizations. Funding for technical assistance will range from \$4 to \$5 million.

A. Timing and Duration of Awards

We expect all grant awards to be made before to October 1, 2001. Grantees may expend grant funds over a 36-month period from the date of the award.

B. Match Requirements

Grantees of the Nursing Facility Transitions, Community PASS, and "Real Choice" grants are required to make a nonfinancial recipient

contribution of 5 percent of the total grant award. Nonfinancial recipient contributions may include the value of goods and/or services contributed by the Grantee, for example, salary and fringe benefits of staff devoting a percentage of their time to the grant not otherwise included in the budget or derived from Federal funds. Recipient contributions must be included in the Applicant's Budget on Standard Form 424A. The nonfinancial match requirement may also be satisfied if a third party participating in the grant makes an "in-kind contribution," provided that the Grantee's contribution and/or the third-party in-kind contribution equals 5 percent of the total grant award. Third-party "in-kind contributions" may include the value of the time spent by consumer task force members (using appropriate cost allocation methods to the extent that non-Federal funds are involved) who specifically contribute to the design, development, and implementation of the grant.

Grantees applying for the National Technical Assistance Exchange for Community Living grant will be required to make a nonfinancial recipient contribution of 1 percent of the total grant award. Applicants must specify these required recipient contributions in their Budget on Standard Form 424A.

C. Indirect Costs

Reimbursement of indirect costs under each of the four grant solicitations is governed by the provisions of the U.S. Department of Health and Human Services, Grants Policy Directive (GPD) Part 3.01: Post-Award—Indirect Costs and Other Cost Policies. We recommend that applicants review the provisions of this policy directive and applicable Office of Management and Budget (OMB) circulars in preparing budget information. This information is available in the solicitation and online at: <http://www.hhs.gov/grantsnet/adminis/gpd/gpd301.htm>.

D. Who May Apply

States may apply for *any* grant, except the Independent Living Partnership portion of the "TRANSITIONS" grant. By "State" we refer to the definition provided under 45 CFR 74.2 as "any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments." By "territory or possession" we mean Guam, the U.S. Virgin Islands, American Samoa, and

¹ Independent Living Centers (ILCs) refer to those ILCs recognized under State or Federal Law.

the Commonwealth of the Northern Mariana Islands.

For the "Real Choice Systems Change" grants and the State Program portion of the "Nursing Facility Transitions" grant, only State agencies or instrumentalities may apply. These agencies must have the support and active participation of one of the following: the Governor, the State Medicaid agency, or the State agency administering a relevant section of the 1915(c) home and community-based waiver.

For the Independent Living Partnership portion of the "Nursing Facility Transitions" grant, only Independent Living Centers may apply. Each Applicant must have (1) the support and active participation from the State Medicaid agency or the State agency administering a relevant section of the 1915(c) home and community-based waiver, and (2) the support and active participation of at least two other consumer-governed organizations.

For the "Community PASS" grants, any State agency or any other organization may apply if it has the support and active participation of one of the following: the Governor, the State Medicaid agency, or the State agency administering a relevant section of the 1915(c) home and community-based waiver.

For the "National Technical Assistance Exchange for Community Living" grant, any organization may apply. However, according to 45 CFR 74.81, no funds may be paid as profit to any recipient organization.

States may and are encouraged to apply for more than one type of grant. For example, a State may apply for a "Real Choice Systems Change" grant and also apply for a "Nursing Facility Transitions" grant. Also, different State agencies may apply for different *types* of grants. For example, the Medicaid agency might apply for a "Community PASS" grant, and the agency administering the section 1915(c) waiver might apply for a "Nursing Facility Transitions" grant. However, no State may be awarded more than one grant per State per type of grant. For example, a State may not receive two "Real Choice Systems Change" grants or

two "Community PASS" grants. Neither an Independent Living Partnership grant nor a technical assistance grant will count against this limit.

In addition, a State, or other eligible entity, may submit a single application for any one type of grant that is composed of multiple, interrelated projects. For example, a State might submit an application for the "Real Choice Systems Change" grant that is composed of a "one-stop shopping" demonstration and a separate but related project to solve the shortage of front-line workers. While only one entity may receive the grant, the Grantee agency may subcontract portions of the award consistent with the Applicant's proposed project. A potential Applicant may request written clarification from us in advance of the application due date if it is unclear whether it is eligible to apply for a particular grant.

HCFA reserves the right to assure reasonable balance in the awarding of grants, in terms of key factors such as geographic distribution, broad target group representation, etc.

E. Involvement of Consumers, Stakeholders, and Public-Private Partnerships

For all grant solicitations, we strongly encourage the continuous, active involvement of consumers in both project design and implementation. We encourage processes that promote the active involvement of all other stakeholders. In addition, we encourage the development of public-private partnerships that make the most effective use of each partner's expertise.

For the "Real Choice Systems Change" grants, the Congress expressed its preference that the grant applications "be developed jointly by the State and the Consumer Task Force. The Task Force should be composed of individuals with disabilities from diverse backgrounds, representatives from organizations that provide services to individuals with disabilities, consumers of long-term services and supports, and those who advocate on behalf of such individuals" (H. Conf. Rep. No. 106-1033 at 150).

We encourage collaboration with a broad range of public and private

organizations whose primary purpose is advocating for people with disabilities or long-term illnesses. Examples of these organizations include State Independent Living Councils, Area Agencies on Aging (AAAs), Developmental Disabilities Councils, State Mental Health Planning Councils, State Assistive Technology Act Projects (AT Act Projects), and other national and statewide consumer disability and aging organizations. We also encourage Applicants to partner with volunteer groups, employers, faith-based service providers, private philanthropic organizations, and other community-based organizations.

For more information regarding the options available to States relative to the consumer task force and other more detailed questions related to these grants, please visit our web site at <http://www.hcfa.gov/medicaid>.

F. Executive Order 12372

Applications for these grants are not subject to review by States under Executive Order 12372, "Intergovernmental Review of Federal Programs" (45 CFR Part 100).

G. Information Collection Requirements

The information collection requirements associated with the solicitation are under review by the Office of Management and Budget. We published a notice in the **Federal Register** on May 10, 2001, to solicit comments on the collection.

Authority: These grants are authorized under section 1110 of the Social Security Act. Funding and Congressional language was provided in the Consolidated Appropriations Act, 2001 (Pub. L. 106-554) (including H.R. 5656 Labor, HHS, and Education Appropriations), and in the accompanying Report, H. Conf. Rep. No. 106-1033. HCFA is the designated HHS agency with administrative responsibility for this grant program. (Catalog of Federal Domestic Assistance Number: 93.779; Research and Demonstrations)

Dated: May 10, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

BILLING CODE 4120-03-U

CHART OF SYSTEMS CHANGE GRANTS FOR COMMUNITY LIVING - FY 2001

Name of Grant	Application Deadline Date	Who May Apply?	Maximum Award	Average Award	Maximum Project Period	Estimated Number of Awards
1. Nursing Facility Transitions grants (CFDA 93.779)						
❖ Independent Living Partnerships	07/20/01	Independent Living Centers*	\$600,000	\$200,000	36 mos.	6-8
❖ State Program grants	07/20/01	Any State Agency*	\$1,200,000	\$600,000	36 mos.	10-18
2. Community-Integrated Personal Assistance Services and Supports grants (CFDA 93.779)	07/20/01	Any Entity*	\$1,200,000	\$600,000	36 mos.	9-12
3. Real Choice Systems Change grants (CFDA 93.779)	07/20/01	State Agency or Instrumentality*	\$3,500,000	\$1,000,000	36 mos.	40
4. National Technical Assistance Exchange for Community Living grant (CFDA 93.779)	07/16/01	Any Entity	\$4-\$5 Million	\$4-\$5 million	36 mos.	1

* Requires the support and active participation of one of the following: the Governor, the State Medicaid agency, or the State agency administering a relevant section of the 1915(c) home and community-based waiver.