

Telephone (404) 639-2603. E-mail address: cas5@cdc.gov.

See also the CDC homepage on the Internet for a copy of this announcement, application and forms: <http://www.cdc.gov>.

Potential applicants may obtain a copy of "Preventing Emerging Infectious Diseases: A Strategy for the 21st Century" through the Centers for Disease Control and Prevention (CDC), National Center for Infectious Diseases, Office of Planning and Health Communication—EP, Mailstop C-14, 1600 Clifton Road, NE., Atlanta, GA 30333 or on the CDC webpage.

Dated: July 6, 1999.

**John L. Williams,**

*Director, Procurement and Grants Office,  
Centers for Disease Control and Prevention  
(CDC).*

[FR Doc. 99-17556 Filed 7-9-99; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[99-01]

#### **New Child Welfare Demonstration Project Proposals Submitted by States for Waivers Pursuant to Section 1130 of the Social Security Act (the Act); Titles IV-E and IV-B of the Act; Public Law 103-432**

**AGENCY:** Administration for Children and Families, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice lists new proposals for child welfare waiver demonstration projects submitted to the Department of Health and Human Services pursuant to the guidance contained in Information Memorandum ACYF-CB-IM-99-03 dated January 21, 1999, public notice of which was given in the **Federal Register** of February 8, 1999, Vol. 64, No. 25, page 6099.

**Comments:** We will accept written comments on these proposals, but will not provide written responses to comments. We will neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

**ADDRESSES:** For specific information or questions on the content of a project or requests for copies of a proposal, contact the State contact person listed for that project.

Comments on a proposal should be addressed to:

Laura Oliven, Children's Bureau, Administration on Children, Youth and Families, 330 C Street, SW, Mary E. Switzer Building, Room 2058, Washington, D.C. 20447. FAX: (202) 260-9345.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Under Section 1130 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) may approve child welfare waiver demonstration project proposals with a broad range of policy objectives.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. The most recent expression of these policies and procedures may be found in the January 21 Information Memorandum cited above, a copy of which may be found at the ACF website at <http://www.acf.dhhs.gov/programs/cb/cww.htm> or may be obtained from the National Clearinghouse on Child Abuse and Neglect Information, (800) 394-3366, internet address <nccanch@calib.com>. We are committed to a thorough and expeditious review of state proposals to conduct child welfare demonstrations.

##### **II. Listing of New Proposals**

As part of our procedures, we are publishing a notice in the **Federal Register** of all new proposals. This notice contains summaries of five new proposals received as of July 6, 1999. Each of the proposals contains an assurance that the proposed demonstration effort will be cost neutral to the federal government over the life of the proposed effort; and each proposal contains an evaluation component designed to assess the effectiveness of the project.

##### *State: Colorado*

**Description:** Colorado proposes to test the impact of contracting with a single provider (or consortium of providers) under a case rate financing model to achieve improved outcomes for children in the target population. Under the case rate, the providers will have a defined amount of resources to achieve case outcomes. Each of the six counties participating in the project will individually negotiate their case rate. One of the most critical aspects of the case rate structure is that providers will be expected to meet child specific outcomes and system performance targets. In addition to the case rate financing structure, the provider will be able to use flexible title IV-E funds to provide an expansive array of

preventive and treatment intervention services. To be eligible for the demonstration, the provider must have access to such services as mental health, substance abuse, transportation, education, post placement services and many more. Because few providers have the full array of services "under one roof" they will need to collaborate to ensure a comprehensive network. The State seeks waivers of child welfare eligibility requirements and restrictions on allowable expenditures for their proposed five year demonstration.

The target population for the project would be children who are at high risk of, or already experiencing "placement drift" and are at significant risk of aging out of the system without a permanent relationship with a family. The State hypothesizes that by converting the financing from fee-for-service to risk-based, performance based contracting, the State will produce improved safety, permanency and well-being outcomes for this population and overall efficiencies in the system. The State will analyze the impact of the project using a random assignment evaluation design.

**Contact Person:** Marva Livingston Hammons, Director, Colorado Department of Human Services, 1575 Sherman Street, 8th Floor, Denver, Colorado 80203-1714, Phone: (303) 866-5700, Fax: (303) 866-4214.

##### *State: Florida*

**Description:** Florida proposes to test the effectiveness of capitating payments and providing flexible use of title IV-E dollars to support and incentivize locally controlled systems of care in select districts to better meet the needs of abused and neglected children and their families. This demonstration will assist the State in meeting its 1998 legislative requirement to develop a plan for privatizing the entire child welfare system, with the exception of child protective service intake and investigations, by the year 2003. Florida plans to conduct this demonstration in at least 8 of its 15 districts. The target population will be all title IV-E and non-title IV-E eligible children and families in each of the demonstration sites who are reported for abuse or neglect with some finding of maltreatment and require services beyond those provided by the department during the investigation phase. Each demonstration site will contract with community-based, nonprofit agencies for the management and delivery of services, using a lead agency community network model. These lead agencies will assume the financial risk for providing all services for all children referred and receive

financial bonuses and penalties linked to performance. In addition, these flexible child welfare services will be coordinated with Medicaid funded behavioral health services.

The State hypothesizes that providing expanded services through community-based systems of care will improve access to services, provide protection from harm for the children served, reduce the length of stay in out-of-home care, reduce re-entry into the foster care system, improve satisfaction ratings of services, and reduce variability in performance across sites.

The State is requesting a waiver of eligibility requirements and services that can be provided using federal title IV-E funds. The evaluation of this five year demonstration will be based on county comparisons.

Contact Person: Margaret Taylor, Florida Department of Children and Families, 1317 Winewood Boulevard, Tallahassee, Florida 32399-0700, Phone: (850) 922-0149, Email: Margaret\_Taylor@dcf.state.fl.us

#### *State: Illinois*

*Description:* The State of Illinois proposes to provide enhanced alcohol and other drug abuse (AODA) and individualized services to families affected by alcohol and other drugs. The purpose of the demonstration is to improve permanency outcomes for children of parents with AODA problems and to reduce the negative impact of parental AODA on children by assisting the family in treatment and recovery. Specifically the project is expected to result in higher rates of reunification, a reduced number of days in foster care and fewer re-allegations of abuse or neglect.

This project will involve two cohorts. Families in the first cohort will be assigned Recovery Coaches who will conduct outreach and support services. Following an additional planning year, families assigned to the second cohort will receive services tailored to their individual needs, in addition to the outreach and support provided by the Recovery Coaches. These services may include medically-managed detoxification and withdrawal, drug-free housing for families, graduated sanctions, reunification/concurrent planning specialists, public health nurses and parental involvement services. Existing aftercare services are available for control group families; Recovery Coaches will access and coordinate aftercare services for experimental group families.

The State hypothesizes that children in the experimental groups will spend fewer average days in foster care, will be

safely reunited with their parents at higher rates, and revictimized at lower rates than children in the control group. The state also postulates that parents in the demonstration groups will successfully complete AODA treatment at a higher proportion than do parents in the control group.

Target populations in Cook County are: (1) custodial parents with a child who enters placement after September 30, 1999; and (2) parents who deliver substance exposed infants. The demonstration will operate for five years. The State will randomly assign families to experimental and control groups following AODA assessment.

The State is requesting a waiver to allow title IV-E funds to be used for services not normally eligible including the maintenance and provision of services to the parent of the ward as well as to operate this demonstration project in selected parts of the state.

Contact Person: Jess McDonald, Director, Illinois Department of Children and Family Services, 100 West Randolph, 6th Floor, Chicago, IL 60601, Phone: (312) 814-4650, Fax: (312) 814-3255.

#### *State: Maryland*

*Description:* The State of Maryland proposes two distinct components for a five year Child Welfare demonstration: intensive substance abuse treatment and supportive services for substance-abusing women; and a child welfare managed care project for children placed in out-of-home care through the Baltimore City Department of Social Services.

The first project would provide gender specific substance abuse treatment in combination with intensive supports and case management from a Family Support Services Team (FSST) to substance abusing mothers whose children are in foster care, or at risk for being placed in foster care. The FSST will consist of Chemical Addiction Counselors (CAC), mentors, parent aides, agency staff and treatment providers. The program is designed to provide a comprehensive and seamless support system to incentivize women to enter into, and complete successful drug and alcohol treatment. The purpose of the project is to prevent unnecessary out-of-home placements and reduce the length of stay of children already placed in foster care. The project would be conducted in Baltimore City and Prince George's County, two jurisdictions in Maryland that experience a high number of foster care placements due to parental substance abuse.

The second project would implement a child welfare managed care pilot

initiative for 1,000 of the children in paid out-of-home placement and committed to the Baltimore City Department of Social Services (BCDSS) by the Baltimore City Juvenile Court. This initiative focuses on accountability and quality outcomes with reimbursement linked to performance. The project proposes to reshape the contractual relationship between the public agency and the private agencies from one of "payment of care" to a "reward for results" system. Providers will be asked to propose outcome improvements that exceed the State outcome goals and current benchmarks. Providers that do not meet the benchmark outcomes will risk financial loss. Those who improve on outcomes will be given the flexibility to redirect cost savings to innovative and enhanced services for project participants. The State expects to produce an increase in permanency with a reduction in the number of foster care days; a decrease in the restrictiveness of placements provided; and a reduction in re-entry into foster care.

Contact Person: Linda D. Ellard, Executive Director, Social Services Administration, 311 West Saratoga Street, Baltimore, MD 21201, Phone: (410) 767-7216, Fax: (410) 333-0127.

#### *State: West Virginia*

*Description:* West Virginia proposes a substance abuse initiative that would allow a child to remain in his/her home or be placed in a temporary setting while the child's mother receives 30-60 day in-patient and/or residential treatment for alcohol or drug abuse. Where possible, the child would be placed in close proximity to the treatment center to enable visitation between the mother and child. The State hypothesizes that by placing the child in a temporary care setting, and avoiding the "formal" foster care system, mothers receiving treatment will be more likely to enter into, and complete, successful treatment. The State expects to reduce the number of children entering into the State's formal foster care system due to parental substance abuse; increase the number of family reunifications after treatment; and increase the number of mothers completing short-term treatment. The State intends to partner with the West Virginia Department of Health and Human Resources, responsible for the care of the state's foster children, with the Division of Alcoholism and Drug Abuse, to assist mothers in overcoming barriers to substance abuse treatment. Following treatment, multidisciplinary teams including Substance Abuse Outreach Specialists and social workers

will continue to provide services to the families to ensure the children's safety and work towards successful reunification.

The State plans to operate this demonstration project in rural counties including Boone, Cabell, Clay, Jackson, Roane, Kanawha, Lincoln, Mason, Mingo, Putnam, and Wayne. The target population includes all youth ages 0–18 who would likely enter formal foster care if their parents do not receive substance abuse treatment, according to formal risk assessments.

The State is requesting a waiver of the placement standards and eligibility requirements. West Virginia plans to assess the impact of the five year demonstration using a random assignment evaluation design.

Contact Person: Ann Burds, Director, Bureau for Children & Families/Office of Social Services, Department of Health and Human Resources, State Capital Complex, Building 6, room 850, Charleston, West Virginia 25305, Phone: (304) 558–7980, Fax: (304) 558–8800.

Dated: July 7, 1999.

**Patricia Montoya,**

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 99–17655 Filed 7–9–99; 8:45 am]

BILLING CODE 4184–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97D–0530]

#### FDA Modernization Act of 1997: Modifications to the List of Recognized Standards

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the publication of modifications to the list of standards that will be recognized for use in the premarket review process. This will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

**DATES:** This recognition of standards is effective on July 12, 1999; however, written comments concerning this document may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of "Modifications to the List of Recognized Standards" to the Division of Small Manufacturers Assistance (DSMA),

Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Written comments concerning this document must be submitted to the listed contact person. Comments should be identified with the docket number found in brackets in the heading of this document. This document may also be accessed via the Internet at FDA's web site "<http://www.fda.gov/cdrh/fedregin.html>". See the **SUPPLEMENTARY INFORMATION** section for electronic access to "Guidance on the Recognition and Use of Consensus Standards," the current list of "FDA Recognized Consensus Standards Appendix A," and other standards related information.

**FOR FURTHER INFORMATION CONTACT:** To comment on this document and/or to recommend additional standards for recognition: James J. McCue, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext. 101.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d) to allow the agency to recognize consensus standards established by international and national standards development organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance document entitled "Recognition and Use of Consensus Standards," which describes how FDA will implement that part of FDAMA. The February 1998 notice also provided the initial list of recognized standards.

In a notice published in the **Federal Register** of October 16, 1998 (63 FR 55617), FDA made modifications to the initial list of recognized standards. This October 1998 notice described the changes made in the initial list and also provided a listing of the "Modifications to the List of Recognized Standards."

##### II. Discussion of Modifications to the List of Recognized Standards

Modifications to the list of consensus standards to be recognized for use in

premarket review and to meet other requirements are presented in a listing at the end of this notice.

Modifications identified in the listing include: (1) The initial addition of certain recognized standards not previously identified by FDA; (2) the addition of certain recognized standards in conjunction with the withdrawal of other previously recognized standards and their replacement by later, amended, or different standards; and (3) the addition of certain recognized standards with revisions to the supplementary information sheets for the standards, involving changes in significant applications of the standards, e.g., changes in the extent of recognition.

The listing of modifications presented at the end of this document does not include minor revisions which the agency is making in certain previously recognized standards. These revisions are made for editorial, corrective, or technical purposes, such as adding a previously omitted date, or changing the contact person(s) in the supplementary information sheet for a recognized standard. Particular minor revisions in the specific recognition of standards are described in the following paragraphs.

As noted previously, FDA is making modifications to the list of recognized standards that represent the initial addition of certain standards not previously recognized by the agency. These additions are identified in the listing presented at the end of this document and are not otherwise described.

Modifications that FDA is making, which represent the addition of certain recognized standards in conjunction with the withdrawal of other standards, or with changes in significant applications of the standards, are also identified in the listing at the end of this document. However, the agency is further describing the actions it is taking in making these additions, and in sections II.A through H of this document it is identifying the minor revisions it is making in certain recognized standards.

##### A. Generally Applicable Standards

1. ANSI/AAMI/ISO 10993–1 and ISO 10993–1 are withdrawn, under previous items 1 and 3,<sup>1</sup> respectively, from the list of recognized consensus standards. The latest version of the standard ISO 10993–1 (1997) is added, under current

<sup>1</sup> Item numbers identify entries in the "FDA Recognized Consensus Standards Appendix A." Within each grouping, entries begin with item 1. Item numbers are not repeated if an entry is withdrawn, replaced, or added.