

submit denominator data for the device identified, which includes the number of devices manufactured and distributed in the last 12 months, an estimate of the number of devices in current use, and a brief description of any methods used to estimate the number of devices distributed and in current use. Based on comments received subsequent to the issuance of the December 11, 1995, final rule, FDA stayed the requirement to submit this denominator data pending further evaluation (61 FR 39868).

During the stay, FDA has two projects planned: (1) A public workshop and (2) a demonstration project. The agency is requesting industry's assistance to accomplish both these projects. In preparation for the demonstration project, CDRH is convening a public workshop to enable the agency to better understand methods used to derive denominator estimates and therefore better evaluate and utilize these data.

For this workshop, CDRH is soliciting speakers from the medical device industry to speak for approximately 10–15 minutes each on methods they use to estimate denominator data. Given that methods may vary by type of device, FDA is interested in hearing from members of the medical industry representing three basic categories of devices: Single use/disposable, multiple use, and implantables. After opening remarks and background presentations by FDA, it is anticipating that the workshop will include a series of presentations by industry members representing these basic device categories in three sessions (one per category) over 1 to 2 days. FDA intends to invite a group of discussants, representing various disciplines (e.g., survey methods, statistics, procurement, marketing, epidemiology), to listen and to respond to the presentations. Several question and answer sessions are also planned for the benefit of attendees.

At the completion of the public workshop and the demonstration project, the agency will either lift the stay of the December 1995 final rule baseline denominator reporting requirements, retain the stay, or issue a new proposed rule to modify these requirements.

Dated: August 12, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20965 Filed 8–15–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration [ORD–090–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: June 1996

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

ACTION: Notice.

SUMMARY: During the month of June, one new proposal for a Medicaid demonstration project was submitted to the Department of Health and Human Services, one proposal was approved and one proposal was withdrawn. No proposals were disapproved during this time period. (This notice can be accessed on the Internet at [HTTP://WWW.HCFA.GOV/ORD/ORDHP1.HTML](http://WWW.HCFA.GOV/ORD/ORDHP1.HTML).)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, 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: Mail correspondence to: Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson, (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the Federal Register (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration

projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the Federal Register with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that such grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, and Withdrawn Proposals for the Month of June 1996

A. Comprehensive Health Reform Programs

1. New Proposals

The following comprehensive health reform proposal was received during the month of June:

Demonstration Title/State: Community Care Systems—New Hampshire.

Description: The State submitted a revised proposal for “Community Care Systems.” This system will provide capitated, managed acute care services and coordination for specialty and support services not included in the health plan service package. The State proposes to implement this program in three phases: Phase 1 will enroll AFDC and AFDC-related children and families; Phase 2 will enroll the elderly population; and Phase 3 will enroll disabled adults and disabled children. The current waiver request is for Phase 1 only.

Date Received: June 5, 1996.

State Contact: Lorrie Lutz, Planning and Policy Development, State of New Hampshire, Department of Health and Human Services, 6 Hazen Drive, Concord, NY 03301–6505, (603) 271–4478.

Federal Project Officer: Cindy Shirk, Health Care Financing Administration, Office of Research and Demonstrations, Office of State Health Reform Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

2. Pending, Approved and Disapproved Proposals

We did not approve or disapprove any proposals during the month of June. The one new proposal submitted in May and now pending is as follows:

Demonstration Title/State: Maryland Medicaid Reform Proposal—Maryland.

Description: A statewide section 1115 demonstration proposal has been developed to: provide a patient-focused system through managed care entities; build on the strengths of the current Maryland health care system; provide comprehensive, prevention-orientated systems of care; hold Managed Care Organizations (MCOs) accountable for high-quality care; and achieve better value and predictability for State expenditures.

Date Received: May 3, 1996.

State Contact: Mary Mussman, M.D., M.P.H., Acting Executive Director, Center for Health Program Development and Management, Social Sciences Building, Room 309A, 5401 Wilkens Avenue, Baltimore, MD 21228-5398, (410)455-6804.

Federal Project Officer: Gina Clemons, Health Care Financing Administration, Office of Research and Demonstrations, Office of State Health Reform Demonstrations, Mail Stop C3-18-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Other pending proposals can be found in the Federal Register of January 23, 1996, 61 FR 1769.

3. Withdrawn Proposals

The following proposal was withdrawn June 4, 1996:

Demonstration Title/State: The Granite State Partnership for Access and Affordability in Health Care—New Hampshire.

B. Other Section 1115 Demonstration Proposals

1. New Proposals

No new proposals were received during the month of June.

2. Approved Proposals

The following proposal was approved during the month of June:

Demonstration Title/State: Medicaid Family Planning Services for Women of Childbearing Age—Arkansas.

Description: This State demonstration will provide Medicaid covered family planning services for all women of childbearing age with incomes at or below 133 percent of the Federal Poverty Level.

Date Received: September 13, 1995 (October 2, 1995 date listed in 61 FR 1771 was not correct).

Date Approved: June 18, 1996.

State Contact: Thomas Dalton, Director, Arkansas Department of Human Services, P.O. Box 1437, Little Rock, Arkansas 72203-1437, (501) 682-8650.

Federal Project Officer: Rosemarie Hakim, Health Care Financing

Administration, Office of Research and Demonstrations, Mail Stop C3-24-07, 7500 Security Boulevard, Baltimore, MD 21244-1850.

3. Pending and Withdrawn Proposals

We did not disapprove any Other Section 1115 Demonstration Proposals during June nor were any proposals withdrawn during that month. Pending proposals for the month of November 1995 published in the Federal Register on January 23, 1996, 61 FR 1769, and for the months of February and March 1996 published in the Federal Register on May 14, 1996, 61 FR 24318 remain unchanged with the exception of the approved proposal as shown above.

III. Requests for Copies of a Proposal

Requests for copies of a specific Medicaid proposal should be made to the State contact listed for the specific proposal. If further help or information is needed, inquiries should be directed to HCFA at the address above.

(Catalog of Federal Domestic Assistance Program, No. 93.779; Health Financing Research, Demonstrations, and Experiments.)

Dated: July 24, 1996.

Barbara Cooper,

Acting Director, Office of Research and Demonstrations.

[FR Doc. 96-20918 Filed 8-15-96; 8:45 am]

BILLING CODE 4120-01-P

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meetings

Pursuant to Public Law 92-463, notice is hereby given of the meetings of the following Heart, Lung, and Blood Special Emphasis Panels.

These meetings will be open to the public to provide concept review of proposed contract or grant solicitations.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contract Persons listed below in advance of the meetings.

Name of Panel: New Therapies for Thalassemia.

Dates of Meeting: September 16, 1996.

Time of Meeting: 10:00 a.m.

Place of Meeting: National Institutes of Health, Rockledge Building II, 6701 Rockledge Drive, Room 10158, Bethesda, Maryland 20892.

Agenda: To develop strategies for implementing clinically-related recommendations from the NHLBI Report on "Cooley's Anemia: Progress in Biology and Medicine—1995" as a future initiative.

Contact Person: Alan S. Levine, NHLBI/DBDR, Two Rockledge Center, 6701

Rockledge Drive, Rm. 10158, MSC 7950, Bethesda, Maryland 20892, Bethesda, Maryland, 20892, (301) 435-0050.

Name of Panel: Bone Marrow Transportation in Sickle Cell Anemia.

Dates of Meeting: September 24, 1996.

Time of Meeting: 10:00 a.m.

Place of Meeting: Natcher Building, LL-Room J, 45 Center Drive, Bethesda, Maryland 20892.

Agenda: To review current progress and identify future research initiatives in the use of bone marrow transplantation for the treatment of Sickle Cell Anemia.

Contact Person: Helena Mishoe, NHLBI/DBDR, Two Rockledge Center, 6701 Rockledge Drive, Rm. 10156, MSC 7950, Bethesda, Maryland 20892, Bethesda, Maryland 20892, (301) 435-0050.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: August 9, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-20941 Filed 8-15-96; 8:45 am]

BILLING CODE 4140-01-M

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the following Heart, Lung, and Blood Special Emphasis Panel.

The meeting will be open to the public to provide concept review of proposed contract or grant solicitations.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

Name of Panel: Cardiac Arrhythmias in Children.

Dates of Meeting: August 29, 1996.

Time of Meeting: 8:30 a.m.

Place of Meeting: Natcher Building 45, Conference Room B, 45 Center Drive, Bethesda, Maryland 20892.

Agenda: To evaluate the nature and severity of arrhythmias occurring in children on psychotropic drugs, and those that occur after cardiac surgery and recommend research priorities for future initiatives.

Contact Person: Thomas J. Doubt, NHLBI/DHVD, Two Rockledge Center, 6701 Rockledge Drive, Room 9044, MSC 7940, Bethesda, Maryland 20892, (301) 435-0540.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle. (Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases