

Washington Room, Thomas Circle, at Massachusetts Ave. & 14th St. NW, Washington, DC, Metro Stop: Blue or Orange line to McPherson Square, Red line to Farragut North.

**Contact:** Michael D. Anderson, Office of Consumer Affairs, (HFE-40), Food and Drug Administration, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857, 301-827-4417, FAX 301-443-9767, E-mail: Manders1@oc.fda.gov.

**Registration:** Send registration information (including name, title, organization, address, telephone, and fax number) to the contact person by March 16, 1998.

If you need special accommodations due to a disability, please contact Michael D. Anderson at least 7 days in advance.

**Supplementary Information:** The purpose of the Forum is to provide an opportunity for consumers and patients to meet with FDA officials to express their views and concerns on regulatory and consumer protection policies and patient protection issues.

**Transcripts:** Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: March 4, 1998.

**William K. Hubbard,**  
Associate Commissioner for Policy  
Coordination.

[FR Doc. 98-6079 Filed 3-9-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 93N-0453]

#### Agency Information Collection Activities; Announcement of OMB Approval

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Human Tissue Intended for Transplantation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezuto, 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 December 11, 1997 (62 FR 65277), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0302. The approval expires on February 28, 2001.

Dated: March 2, 1998.

**William B. Schultz,**  
Deputy Commissioner for Policy.  
[FR Doc. 98-6081 Filed 3-9-98; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[HCFA-2021-N]

#### New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: December 1997 and January 1998

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

**ACTION:** Notice.

**SUMMARY:** One new proposal for a Medicaid demonstration project was submitted to the Department of Health and Human Services during the month of January 1998 under the authority of section 1115 of the Social Security Act. No proposals were received during the month of December 1997. No proposals were approved, disapproved or withdrawn during that time period. (This notice can be accessed on the Internet at <http://www.hcfa.gov/cmso/sect1115.htm>.)

**COMMENTS:** We will accept written comments on this proposal. 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: Gloria Smiddy, Center for Medicaid and State Operations, Health Care Financing

Administration, Mail Stop C3-18-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** Gloria Smiddy, (410) 786-7723.

**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 grant solicitation or other competitive process is reported as received during the month that such grants or bid is awarded, so as to prevent interference with the awards process.

### II. Listing of New, Pending, Approved, Disapproved, and Withdrawn Proposals for the Months of December 1997 and January 1998

#### A. Comprehensive Health Reform Programs

##### 1. New Proposal

The following comprehensive health reform proposal was received during the month of January 1998.

**Demonstration Title/State:** BadgerCare/Wisconsin.

**Description:** The State submitted a proposal that would use a combination of title XIX and title XXI funding to ensure access to health care for all children and parents in uninsured families with incomes below 185

percent of the Federal poverty level. Once enrolled, families would maintain their eligibility until their income reaches 200 percent of the Federal poverty level. The benefits would be identical to the Medicaid benefits package and current provisions for quality assurance under Wisconsin's present Medicaid managed care system.

*Date Received:* January 23, 1998.

*State Contact:* Angie Dombrowicki, Department of Health and Family Services, Division of Health, One West Wilson Street, Room 237, P.O. Box 309, Madison, WI 53701-0309, 608-266-1935.

*Federal Project Officer:* Maria Boulmetis, Health Care Financing Administration, Center for Medicaid and State Operations, Family/Children's Health Program Group, 7500 Security Boulevard, Baltimore, MD 21244-1850.

## 2. Pending Proposals

The pending proposals for July 1997 through November 1997 that are referenced in the **Federal Register** of February 4, 1998 (63 FR 5810) remain unchanged.

## 3. Approved Proposals

No proposals were approved during the months of December 1997 and January 1998.

## 4. Approved Conceptual Proposals (Award for Waivers Pending)

No conceptual proposals were approved during the months of December 1997 and January 1998.

## 5. Disapproved and Withdrawn Proposals

No proposals were disapproved or withdrawn during the months of December 1997 and January 1998.

## B. Other Section 1115 Family Planning Programs

1. *New Proposals:* No new proposals were received during the months of December 1997 and January 1998.

2. *Pending Proposals:* The pending proposals for July 1997 through November 1997 that are referenced in the **Federal Register** of February 4, 1998 (63 FR 5810) remain unchanged.

3. *Approved Conceptual Proposals (Award of Waivers Pending):* No conceptual proposals were approved in the months of December 1997 and January 1998.

4. *Approved/Disapproved/Withdrawn Proposals:* No proposals were approved, disapproved or withdrawn for the months of December 1997 and January 1998.

## 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: February 24, 1998.

**Sally K. Richardson,**

*Director, Center for Medicaid and State Operations.*

[FR Doc. 98-6090 Filed 3-9-98; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration [HCFA-1013-NC]

#### Medicare and Medicaid Programs; Announcement of Additional Application From Hospital Requesting Waiver for Organ Procurement Service Area

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

**ACTION:** Notice with comment period.

**SUMMARY:** This notice announces an additional application that HCFA has received from a hospital requesting waiver from dealing with its designated organ procurement organization (OPO) in accordance with section 1138(a)(2) of the Act. This notice requests comments from OPOs and the general public for our consideration in determining whether such a waiver should be granted.

**DATES:** Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 11, 1998.

**ADDRESSES:** Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1013-NC, PO Box 7517, Baltimore, MD 21244-0517.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments

by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1013-NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

**FOR FURTHER INFORMATION CONTACT:** Mark A. Horney (410) 786-4554.

## SUPPLEMENTARY INFORMATION:

### I. Background

Section 1138(a)(1)(A) of the Social Security Act (the Act) provides that a hospital or rural primary care hospital that participates in the Medicare or Medicaid programs must establish written protocols for the identification of potential organ donors.

Section 155 of the Social Security Act Amendments of 1994 (SSA '94) (Pub. L. 103-432) amended section 1138 of the Act to require that effective January 1, 1996, a hospital must notify the organ procurement organization designated for the service area in which it is located of potential organ donors (sections 1138(a)(1)(A)(iii) and (a)(3)(B) of the Act). The hospital must also have an agreement to do so only with that designated OPO (sections 1138(a)(1)(C) and (a)(3)(A)).

The statute also provides that the hospital may obtain a waiver of these requirements from the Secretary. A waiver would allow the hospital to have an agreement with an "out-of-area" OPO (section 1138(a)(2)) if it meets conditions specified in the statute (section 1138(a)(2)(A)(i) and (ii)).

The law further states that in granting a waiver, the Secretary must determine that such a waiver: (1) Would be expected to increase donations; and (2) will assure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the out-of-area OPO (section 1138(a)(2)(A)). In making a waiver determination, the Secretary may consider, among other factors: (1) Cost effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO service area due to the definition of metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with the out-of-area OPO (section 1138(a)(2)(B)). Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver applications within 30