

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* March 11, 1989. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was March 11, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* December 10, 1993. FDA has verified the applicant's claim that the new drug application (NDA) for TRUSOPT® (NDA 20-408) was initially submitted on December 10, 1993.

3. *The date the application was approved:* December 9, 1994. FDA has verified the applicant's claim that NDA 20-408 was approved on December 9, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,232 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 15, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 12, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 26, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96-12093 Filed 5-13-96; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

[ORD-086-N]

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

AGENCY: Health Care Financing Administration (HCFA).

ACTION: Notice.

SUMMARY: This notice lists new proposals for Medicaid demonstration projects submitted to the Department of Health and Human Services during the months of February and March 1996 under the authority of section 1115 of the Social Security Act. This notice also lists proposals that were approved, disapproved, pending, or withdrawn during this time period. (This notice can be accessed on the Internet at 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 Months of February and March 1996

A. Comprehensive Health Reform Programs

1. New Proposals: The following comprehensive health reform proposal was received during the month of February.

Demonstration Title/State: Medicaid Demonstration Project for Los Angeles County—California.

Description: The State is pursuing a section 1115 demonstration designed to stabilize the Los Angeles County health care system, and to foster a restructuring process that is responsive to the needs of the community in the development of a more cost effective system.

Date Received: February 29, 1996.

State Contact: John Rodriguez, Deputy Director, Medical Care Services, Department of Health Services, 714/744 P Street, P.O. Box 942732, Sacramento, CA 94234-7320, (916) 654-0391.

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.

No new proposals were received during the month of March.

2. Pending, Approved, and Withdrawn Proposals: We did not approve or disapprove any proposals during February or March nor were any proposals withdrawn during those months. The one new pending proposal added to the month of March is: Medicaid Demonstration Project for Los Angeles County—California. See above II.A.1. for further description. Pending proposals for the month of November 1995 published in the Federal Register on January 23, 1996, 61 FR 1769, remain unchanged with the addition of above for the months of February and March.

B. Other Section 1115 Demonstration Proposals

1. New Proposals: The following new proposal was received during the month of February.

Demonstration Title/State: Wisconsin Partnership Program—Wisconsin.

Description: Wisconsin has submitted Medicare section 222 demonstration and Medicaid section 1115 waiver requests to implement the "Wisconsin Partnership Program" in specific counties of the State. This program will test two innovative models of care, one for frail elderly and one for persons with disabilities, utilizing a multi-disciplinary team to manage care. The team is to include the beneficiary, a nurse practitioner, the beneficiary's choice of primary care physician, and a social worker or independent living coordinator. Consumer choice of care, settings and the manner of service delivery is a key component of the program. The demonstration will test the use of consumer-defined quality indicators to measure and improve the quality of service provided to people who are elderly and people with disabilities.

Date Received: February 28, 1996.

State Contact: Mary Rowin, State of Wisconsin, Department of Health and Social Services, 1 West Wilson Street, P.O. Box 7850, Madison, WI 53707, (608) 261-8885.

Federal Contact: William Clark, Health Care Financing Administration, Office of Research and Demonstrations, Office of Beneficiary and Program Research and Demonstrations, Mail Stop C3-21-06, 7500 Security Boulevard, Baltimore, MD 21244-1850.

No new proposals were received in March.

2. Pending, Approved, and Withdrawn Proposals: We did not approve or disapprove any Comprehensive Health Reform Programs or Other Section 1115 Demonstration Proposals during February or March nor were any proposals withdrawn during those months. The one new pending proposal added to the month of March is: Wisconsin Partnership Program—Wisconsin. See above II.B.1. for further description. Pending proposals for the month of November 1995 published in the Federal Register on January 23, 1996, 61 FR 1769, remain unchanged with the addition of above for the months of February and March.

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: April 24, 1996.

Barbara Cooper,

Acting Director, Office of Research and Demonstrations.

[FR Doc. 96-12018 Filed 5-13-96; 8:45 am]

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Health Resources and Services Administration

Advisory Council; Notice of Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory bodies scheduled to meet during the month of June 1996.

Name: National Advisory Council on the National Health Service Corps.

Date and Time: June 6-9, 1996.

Place: Adams Mark Denver Hotel, 1550 Court Place, Denver, Colorado.

The meeting is open to the public.

Agenda: Agenda items include status of NHSC programs and budget, reports on the NHSC alumni study and the NHSC alumni and support network, meetings of NHSC workgroups on State activities, health systems liaison, and alliance development, and site visits to community health centers in the Denver area.

The meeting will begin on Thursday, June 6 at 4:00 p.m. and adjourn at 8:00 p.m. Site visits will occur on Friday morning followed by an afternoon business meeting which will conclude about 5:00 p.m. On Saturday, the meeting will begin at 8:00 a.m. and adjourn at 5:00 p.m. and Sunday's meeting will begin at 8:00 a.m. and adjourn at 12:00 noon.

The meeting is open to the public; however, no transportation will be provided for the site visits. For further information, call Ms. Jewel Davis at (301) 594-4144.

Anyone requiring information regarding the subject Council should contact Ms. Jewel Davis, National Advisory Council on the National Health Service Corps, 8th floor, 4350 East West Highway, Rockville, Maryland 20857, Telephone (301) 594-4144.

Name: Council on Graduate Medical Education.

Date and Time: June 12, 1996, 1:00 p.m.-5:00 p.m.; June 13, 1996, 8:30 a.m.-4:00 p.m.

Place: Omni Shoreham Hotel, 2500 Calvert Street, N.W., Washington, D.C. 20008.

This meeting is open to the Public.

Agenda: The agenda will include two plenary panels to discuss (1) Minorities in Medicine and (2) Medical Education Consortia. There will be reports and updates on the Work Groups: Minorities in Medicine; Geographic Distribution/Medical Education Consortia; Physician Competencies in a

Managed Care World; and IMG entry and Participation in the physician workforce.

Anyone requiring information regarding the subject should contact F. Lawrence Clare, M.D., M.P.H., Deputy Executive Secretary, telephone (301) 443-6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Health Resources and Service Administration, Room 9A-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda Items are subject to change as priorities dictate.

Dated: May 9, 1996.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 96-12094 Filed 5-13-96; 8:45 am]

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National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Notice is hereby given of the meeting of the National Cancer Institute Board of Scientific Advisors Cancer Centers Program Working Group, May 24, 1996 at the Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA.

This meeting will be closed to the public from 8:30 am to adjournment for discussion of confidential issues relating to the review, discussion and evaluation of individual programs and projects conducted by the Cancer Centers Extramural Program. These discussions will reveal confidential trade secrets or commercial property such as patentable material, and personal information including consideration of personnel qualifications and performance, the competence of individual investigators and similar matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Information pertaining to the meeting may be obtained from Dr. Paulette Gray, Executive Secretary, National Cancer Institute Board of Scientific Advisors, National Cancer Institute, 6130 Executive Blvd., EPN, Rm. 600, Bethesda, MD 20892, (301-496-4218).

Dated: May 8, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-12059 Filed 5-13-96; 8:45 am]

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