

approval for the export of the human drug Tomudex® (Paltitrexid) 2 mg powder for infusion and 5 mL clear glass vial to the United Kingdom. This product is used for the treatment of advanced colorectal cancer. The application was received and filed in the Center for Drug Evaluation and Research on May 30, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by July 10, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: June 19, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95-15925 Filed 6-28-95; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

The Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to OMB the following proposals for the collection of information in compliance with the Paperwork Reduction Act (Public Law 96-511).

1. *Type of Request:* Reinstatement, without change of a previously approved collection for which approval has expired; *Title of Information Collection:* Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Report; *Form No.:* HCFA-416; *Use:* States are required to submit annual EPSDT program reports to HCFA

pursuant to section 1902(a) (43) of the Social Security Act. These reports provide HCFA with data necessary to assess the effectiveness of State EPSDT programs, to develop trend patterns and projections nationally, and to respond to inquiries; *Respondents:* State Medicaid agencies; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours Requested:* 1,568.

Additional Information or Comments: Call the Reports Clearance Office on (410) 786-1326 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95-15775 Filed 6-28-95; 8:45 am]

BILLING CODE 4120-03-P

Health Resources and Services Administration

HIV Emergency Relief Grant Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of grants made to eligible metropolitan areas.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that fiscal year 1995 funds have been awarded to the 42 eligible metropolitan areas (EMAs) that have been the most severely affected by the HIV epidemic. Although these funds have already been awarded to the EMAs, HRSA is publishing this notice to inform the general public of the existence of the funds. In addition, HRSA determined that it would be useful for the general public to be aware of the structure of the HIV Emergency Relief Grant Program and the statutory requirements governing the use of the funds.

The purposes of these funds are to deliver or enhance HIV-related (1) outpatient and ambulatory health and support services, including case management and comprehensive treatment services, for individuals and families with HIV disease; and (2) inpatient case management services that prevent unnecessary hospitalization or that expedite discharge, as medically

appropriate, from inpatient facilities. The HIV Emergency Relief Grant Program was authorized by Title I of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, Public Law 101-381, which amended Title XXVI of the Public Health Service Act. Funds were appropriated under Public Law 103-333.

FOR FURTHER INFORMATION CONTACT: Individuals interested in the Title I HIV Emergency Relief Grant Program should contact the Office of the Chief Elected Official (CEO) in their locality, and may obtain information on their CEO contact by calling Anita Eichler, M.P.H., Director, Division of HIV Services, at (301) 443-6745.

SUPPLEMENTARY INFORMATION:

Availability of Funds

A total of \$349,370,000 was made available for the Title I HIV Emergency Relief Grant Program. Of the amount available, 50 percent was allocated to the 42 EMAs according to a formula based on the number and incidence of AIDS cases reported to the Centers for Disease Control and Prevention (CDC) as of March 31, 1994. The other 50 percent was awarded competitively to the EMAs as supplemental grants. Below is a distribution of grants made to the 42 EMAs.

Grantee	Total award
Alameda County CA (Oakland).	\$4,148,299
Austin TX	2,124,274
Baltimore MD	4,715,150
Bergen-Passaic NJ	2,847,639
Boston MA	7,079,242
Broward County FL (Ft. Lauderdale).	5,091,994
Caguas PR	902,928
Chicago IL	12,099,865
Dallas County TX (Dallas)	8,176,385
Denver CO	3,092,041
Detroit MI	2,406,902
Dutchess County NY	609,583
Fulton County GA (Atlanta) ..	9,091,331
Harris County TX (Houston) .	10,233,981
Hudson County NJ (Jersey City).	3,770,366
Jacksonville FL	2,418,868
Kansas City MO	2,726,195
Los Angeles CA	31,037,580
Metro-Dade County FL (Miami).	19,195,347
Nassau/Suffolk NY	3,895,849
New Haven CT	2,711,634
New Orleans LA	3,503,009
New York City NY	93,587,184
Newark NJ	11,791,405
Orange County CA	3,175,288
Orange County FL (Orlando)	3,194,835
Philadelphia PA	9,836,096
Phoenix AZ	2,447,784
Ponce PR	1,908,071
Portland OR	2,402,734

Grantee	Total award
San Antonio TX	1,731,222
San Bernardino CA	2,656,331
San Diego CA	5,628,252
San Francisco CA	31,969,914
San Juan PR	10,269,416
Seattle WA	4,048,484
Sonoma County CA (Santa Rosa)	1,207,605
St Louis MO	2,581,330
Tampa/St Petersburg FL	4,231,119
Vineland NJ	340,644
Washington, DC	10,713,183
West Palm Beach FL	3,770,641

Eligible Grantees

Metropolitan areas which were eligible for grant awards under Title I were those areas for which, as of March 31, 1994, there had been reported to and confirmed by the CDC a cumulative total of more than 2,000 cases of AIDS; or, for which the per capita incidence of cumulative cases of AIDS was not less than 0.0025, as computed on the basis of the most recently available data reported to CDC for the population in the area.

Grants were awarded to the chief elected official of the city or urban county in each EMA that administers the public health agency providing outpatient and ambulatory services to the greatest number of individuals with AIDS.

To be eligible for assistance under Title I, the CEO was required to establish or designate an HIV health services planning council to: (1) Establish priorities for the allocation of funds within the eligible area; (2) develop a comprehensive plan for the organization and delivery of health services described in the statute that is compatible with any State or local plan regarding the provision of health services to individuals with HIV disease; and (3) assess the efficiency of the administrative mechanism in rapidly allocating funds to the areas of greatest need within the eligible area. The planning council must include representatives of: Health care providers; community-based and AIDS service organizations; social services providers; mental health services providers; local public health agencies; hospital planning agencies or health care planning agencies; affected communities, including individuals with HIV disease; non-elected community leaders; State government; and grantees receiving categorical grants for early intervention services under Title III of the CARE Act. The allocation of funds and services within the EMA must be made in accordance with the

priorities established by the planning council.

To be eligible to receive a grant under Title I, the EMAs were required to submit an application containing such information as the Secretary required, including assurances adequate to ensure:

- That funds received would be utilized to supplement not supplant State funds provided for HIV-related services;

- That the political subdivisions within the EMA would maintain HIV-related expenditures at a level equal to that expended for the 1-year period preceding the first fiscal year for which the grant was received. Funds received under Title I may not be used in maintaining the required level of expenditures;

- That the EMA has an HIV health services planning council and has entered into intergovernmental agreements with any required political subdivisions and has developed or will develop a comprehensive plan for the organization and delivery of health services, in accordance with the legislation;

- That entities within the EMA that receive Title I funds will participate in an established HIV community-based continuum of care if such continuum exists within the EMA;

- That Title I funds will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program, or (2) by an entity that provides health services on a prepaid basis; and

- To the maximum extent practicable, that HIV health care and support services provided with Title I assistance will be provided and without regard to the current or past health condition of the individual. Such services will be provided in a setting that is accessible to low-income individuals with HIV disease, and a program of outreach will be provided to inform such individuals of such services.

General Use of Grant Funds

EMAs must use the Title I HIV Emergency Relief grants to provide financial assistance to public or nonprofit entities, for the purpose of delivering or enhancing—

- HIV-related outpatient and ambulatory health and support services, including case management and comprehensive treatment services, for

individuals and families with HIV disease; and

- HIV-related inpatient case management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities.

Services supported by the Title I grant funds must be accessible to low-income individuals and families, including women and children with HIV infection, minorities, and homeless, and persons affected by chemical dependency.

Federal Smoke-Free Compliance

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-277, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or, in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Executive Order 12372

Grants awarded for the Title I HIV Emergency Relief Grant Program are subject to the provisions of Executive Order 12372, as implemented under 45 CFR Part 100, which allows States the option of setting up a system for reviewing applications within their States for assistance under certain Federal programs. The application packages made available by HRSA to the EMAs contained a listing of States which have chosen to set up such a review system and provided a point of contact in the States for the review.

The catalog of Federal Domestic Assistance Numbers are: Formula Grants—93.915; Supplemental Grants—93.914.

Dated: June 23, 1995.

Ciro V. Sumaya,

Administrator.

[FR Doc. 95-15970 Filed 6-28-95; 8:45 am]

BILLING CODE 4160-15-M

HIV Care Grant Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of grants made to States and territories.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that fiscal year 1995 funds have been awarded to States and territories (hereinafter States) for the HIV Care Grant Program. Although these funds have already been awarded to the States, HRSA is publishing this notice to