

notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that

FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant: in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of the PMA applications reviewed within CBER, for which summaries of safety and

effectiveness were placed on the Internet in accordance with the procedure as explained previously through September 30, 1999. There were no denial actions during this period. The list is in order by PMA number and provides the manufacturer's name, the generic name or trade name, and the approval date.

TABLE 1.—LIST OF APPROVAL PMA'S FROM JULY 2, 1999, THROUGH SEPTEMBER 30, 1999

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
BP 97-0001/01/00M-1031	Nexell Therapeutics, Inc.	Isolex 300 Magnetic Cell Selection System and Isolex 300i	July 2, 1999
BP 97-0003/00M-1032	Dendreon Corp.	Magnetic Cell Selection System DACS™SC	July 23, 1999

Dated: March 23, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

State Planning Grants

AGENCY: Health Resources and Services Administration.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of \$15 million to support up to 10 State grants for the development of plans to provide access to health insurance coverage for all State residents. This funding has been appropriated under the Fiscal Year (FY) 2000 HHS Appropriations Act.

In FY 2000, HRSA, through its State Planning Grants Program (SPG), will accept applications from States for fiscal year (FY 2000) grants to conduct a one year, in-depth analysis and related activities necessary to develop the most effective methods for providing access to affordable health insurance coverage to all its citizens. States will be expected to design approaches that provide affordable health insurance benefits similar in scope to the Federal Employees Health Benefit Plan, Medicaid, coverage offered to State employees or other similar quality benchmarks. Each State receiving such grants must submit the study and analysis results in the form of a report to the Secretary that identifies the characteristics of the uninsured within

the State and proposals for providing them with access to health insurance coverage. Together, these reports will provide additional data about the characteristics of the uninsured generally and potential models for other States seeking to provide comprehensive coverage.

DATES: The time line for application submission, review, and award is follows:

April 10, 2000—Application kits (PHS 5161, OMB 0920-0528) and additional guidance will be available through the HRSA Grants Application Center (GAC). To receive a complete application kit, contact the GAC at 1-877-HRSA-123.

April 26 and 28, 2000—Two pre-application workshops are anticipated at Denver, CO (April 26, 2000) and Philadelphia, PA (April 28, 2000). For more information concerning these workshops, contact the State Planning Grant Program Office at 301-443-4619.

July 10, 2000—Applications due.

August 1-4, 2000—Applications reviewed.

September 30, 2000—Grant awards announced.

ADDRESSES: To receive a complete application kit (*i.e.*, application instructions, necessary forms, and application review criteria), contact the HRSA GAC at: HRSA, GAC, 1815 N. Fort Meyer Drive, Suite 300, Arlington, VA 22209, Phone: 1-877-HRSA-123, Fax: 1-877-HRSA-345, E-Mail: hrsagac@hrsa.gov

FOR FURTHER INFORMATION CONTACT: For further information contact Dr. Marcia Brand, Health Resources and Services Administration, Parklawn Building, Room 11-25, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 443-4619, Fax: (301) 443-0643.

SUPPLEMENTARY INFORMATION: In 1998, 44.5 million people in the United States did not have health insurance. This is roughly one out of every six non-elderly Americans. Of these, 24.6 million were employed—18.7 million worked full time and 5.9 million worked part time. Nationally, over 11 million children (*i.e.*, one in seven) are uninsured. Every year, approximately a million Americans lose their health coverage. A poll conducted for Health Coverage 2000 and released in October showed that seven out of ten Americans believe government must address the problem of the uninsured and state that they support \$100 in new taxes to help provide additional health coverage. There is considerable public and private support for examining and implementing new models for providing access to affordable health coverage.

Many States have expressed interest in expanding coverage for the uninsured. Every State has responded to the opportunity provided by the State Children's Health Insurance Program (SCHIP) to design a program that provides health insurance coverage for uninsured low-income children. Many States have also expanded Medicaid coverage to uninsured children and adults, using existing options, such as section 1115 waiver authority, as well as increased flexibility under welfare reform to cover working parents. In addition, many States are assessing State policy in light of recent changes in Medicare. Some States are working towards enhancing coordination of publicly-funded health programs, such as health departments and community health centers. States have also undertaken activities that seek to expand insurance coverage through mechanisms other than Federally-

financed programs (e.g., high risk pools and insurance market changes).

The private sector has expressed an interest in supporting States' efforts to expand coverage for the uninsured. The Robert Wood Johnson Foundation has implemented the State Coverage Initiatives (SCI), a major new technical assistance endeavor that will build on the successes and lessons learned in its earlier States Initiatives in Health Care Reform. The new program seeks to improve the practical capacity of State governments in their quest to decrease the number of uninsured Americans and has an emphasis on policy development and technical assistance. The SCI Program provides resources for technical assistance that States can use to analyze data, diagnose problems, identify solutions, and develop new strategies and policies. It offers small policy planning grants and for a few States, larger scale demonstration grants.

In January 2000, the Robert Wood Johnson Foundation, with the Health Insurance Association of America and Families USA, announced its Health Coverage 2000—Meeting the Challenge of the Uninsured initiative. Through this effort, eight of the nation's leading trade, professional and consumer organizations joined representatives of business, labor, physicians, nurses, hospitals, insurance companies and consumers to propose specific solutions for expanding access to health coverage. During this national conference, these organizations agreed that it is critically important for the health insurance industry to join with other organizations to find ways to promote health coverage for uninsured individuals. Of the eight proposals to expand health insurance coverage to low-income individuals developed at the conference, seven would expand Medicaid, SCHIP, or other government programs to increase coverage.

At the Federal level, the DHHS is committed to assisting States as they examine their options for expanding health insurance benefits. By providing State planning grants, the HRSA State Planning Grants Program intends to encourage States to provide access to affordable health insurance coverage for all its citizens. Each grantee State will receive resources for necessary planning and a coordinated DHHS policy environment. Together, the results of each State's analysis of its uninsured population and its proposals for providing these individuals with access to health insurance coverage will provide additional data about the characteristics of the uninsured generally and present models for other

States seeking to provide such comprehensive coverage.

SPG shares some of the same goals as and focus of the Robert Wood Johnson Foundation's State Coverage Initiatives and the Health Policy Studies Division of the National Governors' Association Center for Best Practices. Thus, whenever possible, SPG will coordinate its efforts with activities of these programs to share information about insurance trends, best practices, data and analyses, and technical assistance.

State Planning Grants

Program Purpose

The purpose of SPG is to have each grantee State develop a plan or propose options that would ensure every citizen in that State access to affordable health insurance benefits similar in scope to the Federal Employees Health Benefit Plan, Medicaid, benefits offered to State employees or other similar quality benchmarks. Not only will the grantee State benefit from its analysis, but by submitting a summary of this analysis and proposed plan at the end of the grant period in a report to the Secretary, other States may learn about successful or innovative ways to provide access to coverage. In addition, DHHS will have the opportunity to review these reports and gain insight into effective methods of supporting such endeavors.

Program Goal

The overarching SPG goal is to encourage States to provide access to health insurance coverage to all citizens by providing the resources needed to develop successful plans and to provide a number of data collection and planning strategies, along with viable insurance expansion options to consider. The immediate goal of SPG is to assist States as they collect and analyze data, develop coverage options or design programs that provide health insurance coverage to all uninsured citizens in the State through expanded State, Federal, and private partnerships.

Program Description

The \$15 million in available funding has been appropriated under the FY 2000 Labor-HHS Appropriations Act. The HRSA, Office of the Administrator, State Planning Grants Program, will oversee the program. Up to 10 awards are anticipated and will vary in size, with a typical grant not to exceed \$1.3 million. Preference will be given to States with lower rates of uninsured, unless the applicant shows a potential for a significant decrease in its uninsured population. Grant awards will reflect diverse State characteristics

(e.g., rural/frontier/urban areas and high/low penetration of managed care) and represent a variety of geographic areas of the country.

During FY 2000, SPG will support one-year planning grants to States to (1) collect and analyze data that describe the characteristics of their uninsured and assist in the design of approaches to provide access to affordable coverage, (2) design a program that would provide all uninsured with access to insurance benefits similar in care to State employee coverage, Federal Employees Health Benefit Plan, Medicaid or other similar quality benchmarks, through a State, Federal, and private partnership, (3) prepare a report to the Secretary describing these findings, and (4) by September 30, 2001, provide the report to the Secretary describing proposals for an expanded State, Federal, and private partnership to cover all of their uninsured.

The successful State applicant will have a demonstrated commitment to reducing its uninsured population; will demonstrate commitment by its Governor and Executive Branch to studying the possibilities for providing health insurance coverage to all uninsured; and will present a comprehensive proposal for the kinds of data to be collected, analysis of that data, use of the analyses to create an approach for covering all uninsured, and a strategy for implementing and funding that approach. The successful applicant will work with all appropriate health-related State agencies, including the Medicaid agency, the budget office, and other relevant departments (e.g., insurance, public health, human services, mental health and substance abuse, and aging). If possible, the applicant should demonstrate communication with the health committees in the State legislature about the proposal. Formal collaboration must exist with private sector organizations (including both business and the health care provider communities), consumer groups, and researchers.

We are looking for applicants with a clear commitment to the goal of providing coverage to all uninsured and an operational plan for using these planning grants to help achieve that goal. As such, funded State planning grants will contain these common elements:

A goal of providing access to affordable health insurance coverage to all citizens in the State—Access to affordable coverage for this grant program means that individuals or families have the opportunity to purchase health insurance coverage or participate in a program that provides

adequate benefits at an affordable cost. States may ensure "affordability" by determining cost-sharing based on the beneficiary's income level and applying a sliding scale related to income, or implementing other cost-sharing protections such as spending caps. For example, in non-Medicaid SCHIP programs, for children in families with income levels above 150 percent of the Federal poverty line, cost-sharing may be imposed on a sliding scale related to income, but the total annual aggregate cost-sharing for all targeted low-income children in the family cannot exceed 5 percent of the family's annual income.

Citizens of the State—If Federal funds are proposed to be used, States should plan their coverage options based on existing Federal eligibility criteria for participation in the Medicaid, SCHIP, and Medicare programs. States may use State funds or other resources to cover non-citizen residents.

Commitment to eliminating the number of uninsured—Grantee States must demonstrate prior efforts, whether or not approved by their State Legislatures, to reduce their number of uninsured through program expansions, data collection activities to support further expansions and/or other activities demonstrating a commitment to providing increased access to health insurance.

Low rates of uninsured—Grantee States should have low rates of uninsured at the time of application submission or the potential for a significant decrease in their uninsured population.

Collaboration among State, Federal, and private partners—Grantee States should build upon current collaborations among State, Federal, and private partners for expanding health insurance coverage to all citizens within the State. States are encouraged to consult with Tribal governments, where appropriate. These collaborations should be formal and should include the leadership of public and private partners.

Capacity for data collection and analysis—Grantee States should demonstrate data collection and analytical capacity or a detailed plan for acquiring this technical assistance, including a commitment from the agency/organization to provide this technical assistance. States are encouraged to work with the many existing Federal and State data collection activities, as well as ongoing efforts in the private, non-profit sector.

Eligible Applicants

Eligibility is limited to States with only one application per State

permitted. The Governor of each State is invited to apply. Each Governor is asked to designate an individual or agency responsible for preparing the State's grant application. A letter from the Governor authorizing this individual or agency to prepare the State's application should accompany the application.

Funding Criteria

Review criteria that will be used to evaluate applications includes:

Evidence that the State has a low rate of uninsured or a justification for its ability to significantly decrease a relatively high level of uninsured.

Evidence of commitment by the Governor, State agencies, and public and private health care providers to provide coverage to all uninsured.

Evidence of prior data collection and analysis resulting in efforts to expand coverage to the uninsured.

Evidence of meaningful collaboration between the agencies and constituencies in the public and private sectors necessary to successfully complete the analysis and submit the required report to the Secretary.

A demonstrated understanding of the technical capacity, resources, and collaboration necessary to successfully carry out the proposed analysis and provide the required report to the Secretary.

An accountable management and budget plan with time lines, demonstrating readiness of the State government to conduct the data collection, analyze the data, develop approaches to providing access to coverage, and determine strategies for implementing and funding such approaches. States should provide an explanation of how they will contract for needed technical assistance, if necessary.

Report Contents

This grant funding will assist States to develop models for providing access to health insurance coverage for all citizens of the State. As a result, each grantee State will prepare a report to the Secretary that provides:

A detailed plan for data collection and analysis, upon which the State will base its design for covering its uninsured.

Its strategy for gaining collaboration and consensus among State, Federal, and private partners on options to expand health insurance coverage to all citizens.

Options for expanding health insurance coverage through State, Federal, and private partnerships. For each option, the grantee State will describe how it proposes to address

these issues: (1) targeting expansion groups such as parents of SCHIP children, young adults ages 19–20, and early retirees; (2) delivery systems; (3) administration; (4) outreach; (5) eligibility levels; (6) eligibility determination process; (7) enrollment process; (8) marketing plan; (9) coverage and benefits (similar to State, Federal employees, Medicaid, and other credible coverage); (10) portability; (11) cost-sharing (co-pays, premiums); (12) integration with existing public and private programs (e.g., Medicaid, Medicare, and SCHIP coverage, State programs, projects proposed through the Community Access Program, *See Federal Register* notice, February 4, 2000); (13) plans for studying or avoiding crowd-out-interaction with employer-sponsored insurance; (14) cost-containment; (15) ensuring quality; (16) ensuring access; (17) data collection; (18) audits; (19) program budget; (20) program evaluations; (21) funding; (22) maintenance of effort; (23) necessary waivers (under existing program authority); (24) necessary State or Federal legislative changes (not under current authority); and (25) private sector options (e.g., high risk pools, employer options, market reforms). States that propose or prepare waivers or State plan amendments (e.g., Medicaid waivers, SCHIP amendments) as a result of their grant activities must submit their requests through existing review processes established by the Health Care Financing Administration.

Use of Grant Funds

Funding provided through this program may not be used to substitute for or duplicate funds currently supporting similar activities. In addition, grant funds may not be used to support construction, renovation or modernization costs. However, grant funds may support costs such as project staff salaries, consultants, project-related travel, project evaluation, limited equipment and software purchases or leases and coordinating project-related meetings.

Expected Results

The implementation of State Planning grants is expected to result in the development of a plan that the State might subsequently implement to provide health insurance coverage to all citizens of the State. In addition, the grantee States will provide information about data collection activities, partnerships, and options that other States may draw from in their efforts to expand health insurance coverage.

Dated: March 27, 2000.

Claude Earl Fox,

Administrator, Health Resources and Services Administration.

[FR Doc. 00-8039 Filed 3-30-00; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4565-N-10]

Notice of Proposed Information Collection: Comment Request; Housing Development Grant Program Project Settlement Procedures

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* May 30, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, L'Enfant Building, Room 8202, Washington, D.C. 20410, telephone (202) 708-5221 (this is not a toll-free number) for copies of the proposed forms and other available information.

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Multifamily Housing, Office of Business Products, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708-3000, (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the

information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitted electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Housing Development Grant Program Project Settlement Procedures.

OMB Control Number, if applicable: 2502-0382.

Description of the need for the information and proposed use: The collection of project settlement information is necessary to implement the program regulation at 24 CFR Part 850—Housing Development Grant. This section of the regulation requires, upon construction completion, that the program respondents account for funds expended. Such accounting is provided through the project settlement process.

Agency form numbers, if applicable: HUD-90024, HUD-90025, HUD-90026, HUD-90028, HUD-90028, HUD-90031.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated number of respondents are 15, the frequency of responses is one, the annual responses are 15, the estimated burden for each form is HUD-90024 (.50 hours per response); HUD-90025 (6 hours per response); HUD-90026 (.50 hours per response); HUD-90027 (.50 hours per response); HUD-90028 (.50 hours per response); and HUD-90031 (8 hours per response); and the annual burden hours requested is 240 per application package.

Status of the proposed information collection: Reinstatement without change.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: March 24, 2000.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 00-7947 Filed 3-30-00; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4566-N-03]

Notice of Submission of Proposed Information Collection to OMB; Emergency Comment Request Youthbuild Program

AGENCY: Officer of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 7, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB approval number (2506-0142) and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Officer of Management and Budget, New Executive Office Building, Washington, DC 20410 (202) 395-7316.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410; e-mail Wayne Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708-5221. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the