

statutory requirements, and to report on planned versus actual performance. The plan was published in November 1998. This report identifies accomplishments against that plan. As this report shows, in fiscal year 1999, FDA achieved significant gains in the six FDAMA objectives by combining the agency's traditional principles and practices with new approaches. In keeping with its traditional values, FDA continued providing a broad spectrum of consumer protections based on rigorous science-based standards. To strengthen its performance, FDA developed partnerships with stakeholders and stimulated cooperation and participation by making its activities more understandable and accessible to stakeholders. FDA's accomplishments include the following:

- New drugs and biological products are being reviewed and released to the public in record time,
- A nationwide food safety surveillance network has now been established which is helping to significantly reduce food-related illnesses and deaths, and
- Millions of consumers have wider and more timely access to information about their new medications.

FDA will continue working with Congress and our stakeholders to improve performance and to work towards meeting our statutory obligations under FDAMA.

Dated: October 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-28616 Filed 11-7-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Universal Newborn Hearing Screening and Intervention

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that approximately \$5 million in fiscal year (FY) 2001 funds is anticipated for 25 to 31 grants to States for the implementation of universal physiologic newborn hearing screening prior to hospital discharge with linkages to medical home, ongoing family-to-family support, diagnostic evaluation by three months of age, and enrollment in a program of early intervention by six

months of age for those infants identified with hearing loss. All awards will be made under the program authority of Title VI of the Labor-HHS-Education Appropriations Act for FY 2000 (Pub. L. 106-113). This Universal Newborn Hearing Screening and Intervention Program (CFDA #93.251) will be administered by the Maternal and Child Health Bureau (MCHB), HRSA. Projects will be approved for a 4-year period, with awards at average yearly amounts ranging from \$100,000 to \$200,000. Funding for Universal Newborn Hearing Screening and Intervention grants is contingent upon the availability of FY 2001 funds.

DATES: Entities which intend to submit an application for this grant program are expected to notify MCHB's Division of Services for Children with Special Health Care Needs by November 10, 2000. The deadline for receipt of applications is December 8, 2000. Applications will be considered "on time" if they are either received on or before the deadline date or postmarked on or before the deadline date. The project award date is March 31, 2001.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1-877-477-2123 (1-877-HRSA-123) beginning November 3, 2000, or register on-line at: <http://www.hrsa.dhhs.gov/>, or by accessing http://www.hrsa.gov/g_order3.htm directly. This program uses the standard Form PHS 5161-1 (rev. 7/00) for applications (approved under OMB No. 0920-0428). Applicants must use Catalog of Federal Domestic Assistance (CFDA) number 93.251 when requesting application materials. The CFDA is a Government wide compendium of enumerated Federal programs, projects, services, and activities which provide assistance. All applications should be mailed or delivered to: Grants Management Officer, MCHB; HRSA Grants Application Center, 1815 N. Fort Meyer Drive, Suite 300, Arlington, Virginia 22209; telephone: 1-877-477-2123; E-mail: hrsagac@hrsa.gov.

This application guidance and the required forms for the Universal Newborn Screening and Intervention program may be downloaded in either WordPerfect 6.1 or Adobe Acrobat format (.pdf) from the MCHB Home Page at <http://www.mchb.hrsa.gov/>. Please contact Joni Johns, at 301/443-2088, or jjohns@hrsa.gov, if you need technical assistance in accessing the MCHB Home Page via the Internet.

This announcement will appear in the **Federal Register** and on the HRSA Home Page at: <http://www.hrsa.dhhs.gov/>.

www.hrsa.dhhs.gov/. **Federal Register** notices are found by following instructions at: http://www.access.gpo.gov/su_docs/aces/aces140.html.

Letter of Intent: Notification of intent to apply can be made in one of three ways: telephone, 301-443-2370; email, iforsman@hrsa.gov; mail, MCHB, HRSA; Division of Children with Special Health Care Needs; Parklawn Building, Room 18A-18; 5600 Fishers Lane; Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Irene Forsman, M.S., R.N., 301/443-2370, email: iforsman@hrsa.gov/ (for questions specific to project activities of the program, program objectives, or the required Letter of Intent which is further described in the application kit); Paulette Faga, 301/443-6934, email pfagan@hrsa.gov/ (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION:

Universal Newborn Hearing Screening and Intervention Program Background and Objectives

HRSA's Maternal and Child Health Bureau has been involved in newborn screening and genetic testing for more than a decade. In 1989, Dr. C. Everett Koop, then Surgeon General, urged that all infants with significant hearing loss be identified by 12 months of age, and encouraged inclusion of this goal in the Public Health Service's "National Healthy People Goals 2000." Since then, MCHB, acting in concert with the Centers for Disease Control and prevention (CDC) and the National Institutes of Health (NIH), has made substantial progress in the adoption of universal newborn hearing screening and early intervention as the standard of care in the United States. The new "Healthy People 2010" includes a revised newborn hearing screening goal of identifying all newborns with significant hearing loss and enrolling them in a program of early intervention by age 6 months. All relevant professional organizations, including the American Academy of Pediatrics, have endorsed the concept.

Also in 1989, MCHB's Division of Services for Children with Special Health Needs began efforts under the Special Projects of Regional and National Significance (SPRANS) authority of the Maternal and Child Health (MCH) Block Grant (Title V of the Social Security Act) to support implementation of universal newborn hearing screening prior to discharge through a series of demonstration projects to assess the effectiveness of new technologies and to provide

technical assistance to a number of hospitals and States in establishing and maintaining universal newborn hearing screening and intervention programs. Resources developed by these projects can be found on-line at: <http://www.usa.edu:8080/-ncham/consort.html>, and <http://www.colorado.edu/slhs/MDNC/index.html>. This grant program will continue to operate in conjunction with the State Title V programs.

In 1999, following more than a decade of pioneering work in universal newborn hearing screening in hospitals nationwide, MCHB released a guide for hospitals wishing to initiate newborn hearing screening and intervention programs. The publication, "Early Identification of Hearing Loss—Implementing Universal Newborn Hearing Screening Programs," is available free to hospitals and birthing centers around the country through the National Maternal and Child Health Clearinghouse and on the World Wide Web at <http://www.nmchc.org>. The guide is organized into areas to be considered in setting up this type of program, such as determining protocol in the participating hospital; choosing equipment; training; financing; managing data; and talking to parents, physicians, and hospital staff.

By the year 2000, about 35 percent of newborns were being screened for hearing loss before discharge. Hundreds of hospitals operate screening programs. Evidence is clear that implementation of universal newborn hearing screening substantially lowers the age at which children with congenital permanent hearing loss are identified and that children who are identified early do better on school related measures. In addition, technology is available to conduct cost-efficient, physiological screening universally prior to hospital discharge. In 1993, less than 5 percent of all infants were screened for hearing loss prior to hospital discharge. Most established programs are now able to screen more than 95 percent of all newborns prior to discharge and parental acceptance of the screening programs is high. Typically, one to three percent of those screened require referral for diagnostic evaluation. The cost of screening is approximately \$25-\$30 per infant.

As of September 200, about 24 States had enacted laws regarding hearing screening for all newborns. However, the vast majority of hospitals in this country still do not screen all infants prior to discharge.

Congressional support to expand universal newborn hearing screening and intervention to all States grew

throughout the 1990's. In November 1999, Congress acted through both the appropriations and authorization processes to target increased resources to encourage State efforts. New legislative authority, enacted under Title VI of the Labor-HHS-Education Appropriations Act for FY 2000 (Pub. L. 106-113), represented a milestone in the effort to give newborns a healthy start in life.

In March 2000, using \$3 million in FY 2000 funds appropriated under the new authority, MCHB was able to increase support for newborn hearing screening and intervention by awarding grants, totaling \$3 million, to 22 States. These four-year grants are the most recent steps toward assuring that once babies are screened and diagnosed with a hearing loss, they and their families receive appropriate services that are coordinated at the community level with early intervention programs, ongoing family-to-family support and the child's medical home, *i.e.*, regular source of primary health care. Diagnosis is recommended by 3 months of age; intervention by 6 months.

The grants to be awarded under this announcement will extend the initiative MCHB began in March 2000, to an additional 25 to 31 States in FY 2001.

Authorization

Title VI of the Departments of Labor-HHS-Education Appropriations Act for FY 2000 (Pub. L. 106-113).

Purpose

The purpose of these grants is to provide funds to States for the implementation of programs of statewide universal physiologic newborn hearing screening prior to hospital discharge with linkages to medical home, ongoing family-to-family support, diagnostic evaluation by three months of age, and enrollment in a program of early intervention by six months of age for those infants identified with hearing loss.

Eligibility

This program is open to State agencies with the capacity to implement a statewide universal newborn hearing screening and intervention program for all newborn infants in the State.

Funding Level/Project Period

The total funding level for these grants is \$5 million annually over a four-year project period, from March 31, 2001 through March 30, 2005. The project period consists of one or more budget periods, each generally of one year duration.

Funding for this grant program is contingent upon the availability of FY 2001 funds. Continuation of any project from one budget period to the next is subject to satisfactory performance, availability of funds, and program priorities. The initial budget period is expected to be 12 months, with subsequent budget periods being 12 months.

An estimated 25 to 31 awards will be made annually, with average first-year awards ranging from \$100,000 to \$200,000.

Funding Priorities and/or Preferences

Preference will be given to States without a Universal Newborn Hearing Screening and Intervention grant from MCHB.

Review Criteria

Applications for this grant program will be reviewed on the basis of the extent to which they address the following criteria:

(1) The degree to which the applicant provides a complete description of the current status of the State with respect to full implementation of a program of universal newborn hearing screening prior to hospital discharge, linkage to the infant's medical home, audiologic diagnosis by 3 months of age, ongoing family-to-family support and enrollment in a program of early intervention by 6 months.

(2) The degree to which the applicant provides an implementation plan to achieve full implementation of a sustainable statewide universal newborn hearing screening program, defined as the screening of 95 percent of infants prior to hospital discharge or in the first month of life. Elements of such a plan include:

(a) A state level advisory committee with appropriate representation of professionals who will be involved in the screening and followup program, families, and consumers of services for infants with hearing loss;

(b) The structure of the screening program, including informed consent procedures; screening methodology, procedures and personnel; timing and responsibility for documenting and communicating results;

(c) Procedures for assuring timely linkages of identified infants and families with the infant's medical home, ongoing family-to-family support and early intervention services (consistent with Part C of the Individuals with Disabilities Education Act (IDEA) [20 U.S.C. 1431 *et seq.*]).

(d) Procedures for assuring that timely audiologic followup and diagnosis of infants suspected of hearing loss is

carried out, including the availability of appropriately trained audiology personnel;

(e) A description of the data and tracking system for infants suspected to have or identified with significant hearing loss, including a description of relationships to other databases within the States that focus on infants and children, particularly the relationship of the newborn hearing screening data to the newborn metabolic screening data and tracking system and CDC's Early Hearing, Detection and Intervention (EHDI) reporting system; and

(f) A plan for professional and public education about the state newborn hearing screening program.

(3) The extent to which the estimated cost to the Government of the project is reasonable, considering the anticipated results;

(4) The extent to which the project personnel are well qualified by training and/or experience for their roles in the project and the applicant organization has adequate facilities and personnel;

(5) The extent to which the project will be integrated with the administration of MCH Block Grant programs and other related programs in the State.

(6) The inclusion of a well developed plan for evaluation, which documents, with data support, the successes (or failures) at each stage of the screening and intervention program. Funded programs will be required to report annually throughout the life of the grant. Data reporting will include the number of infants screened, number referred for audiologic diagnosis, number and age of infants receiving audiologic diagnosis, number of infants with a medical home, referral to family-to-family support and number and age at which identified infants are enrolled in early intervention services. OMB approval for the data reporting will be sought, as required under the Paperwork Reduction Act of 1995.

Applicants should pay strict attention to addressing the above criteria as they are the basis upon which their applications will be judged.

Executive Order 12372

This program has been determined to be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR Part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages to be made

available under this notice will contain a listing of States which have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their State SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date. (See Part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR Part 100 for a description of the review process and requirements).

Dated: November 2, 2000.

Claude Earl Fox,
Administrator.

[FR Doc. 00-28617 Filed 11-7-00; 8:45 am]

BILLING CODE 4160-15-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4565-N-27]

Notice of Proposed Information Collection For the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation; Comment Request

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: January 8, 2001.

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 Plaza Building, Room 8001, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Allen Fishbein, Senior Advisor for

Government Sponsored Enterprises Oversight, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708-3600, extension 2117, or Sandra Fostek, Office of Government Sponsored Enterprises Oversight, at (202) 708-2224, extension 2233 (these are not toll-free numbers) for copies of 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 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., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Regulation of the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac).

OMB Control Number, if applicable: 2502-0514.

Description of the need for the information and proposed use: This notice requests a revision of a currently approved collection to accommodate additional data requirements necessitated by HUD's recent publication of a new implementing regulation to the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (FHEFSSA). On October 31, 2000, HUD published a rule at 24 CFR Part 81, to become effective January 1, 2001, which increased the levels of required affordable housing goal performance for Fannie Mae and Freddie Mac (the GSEs). The rule also implemented certain changes to HUD's counting rules relative to how mortgages will be credited towards the housing goals and provided special incentives whereby the GSEs could earn additional housing goals credit for certain loan purchase activities. HUD's collection of