

305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Comments for the two draft guidance documents should be kept separate and identified by their respective titles. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidances and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Office of Compliance, Center for Devices and Radiological Health (HFZ-341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4648.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629), enacted on November 28, 1990, amended section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j (f)), providing FDA with the authority to add preproduction design controls to the current good manufacturing practice (CGMP) regulation part 820 (21 CFR part 820). This change in law was based on findings that a significant proportion of device recalls were attributed to faulty product design. FDA found that approximately 44 percent of the quality problems that led to voluntary recall actions during a 6-year period were attributed to errors or deficiencies that had been designed into particular devices and that may have been prevented by adequate design controls. These design-related defects involved both noncritical devices (e.g., patient chair lifts, in vitro diagnostics, and administration sets) and critical devices (e.g., pacemakers and ventilators). Also in 1990, the Department of Health and Human Services' Inspector General conducted a study which reached similar conclusions.

FDA undertook the revision of the CGMP regulation to add the design controls authorized by the SMDA to the CGMP regulation and because the agency believed that it would be beneficial to the public and the medical device industry for the CGMP regulation to be consistent, to the extent possible, with the requirements for quality systems contained in international standards. The agency's extensive efforts to revise the CGMP regulation included making publicly available a working draft of a final rule in July 1995, followed by a public workshop on

August 23, 1995 (see 60 FR 37856, July 24, 1995), and an open public GMP Advisory Committee meeting on September 13 and 14, 1995 (see 60 FR 44037, August 24, 1995). The final regulation, generally referred to as the quality system regulation, is now in the final stages of development.

The "Medical Device Design Control Guidance" and "Do It By Design" draft guidance documents are intended to provide assistance in understanding what design controls are and provide recommendations on how to establish design controls, which would be consistent with the new design control requirements. The draft guidance "Medical Device Design Control Guidance" updates the Center for Devices and Radiological Health's "Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers," announced as a final document in the Federal Register of October 5, 1989 (54 FR 41165). The draft guidance documents are projected to be finalized later this year, soon after the new quality system regulation is published.

II. Significance of a Guidance

A guidance document does not bind FDA or the public, and does not create or confer any rights, privileges, or benefits for or on any person; however, it does represent the agency's current thinking on the subjects discussed therein. The draft guidance documents announced in this notice represent the agency's tentative thinking on design controls and the relationship of human factors with design controls.

III. Request for Comments

Interested persons may, on or before April 30, 1996, submit to the Dockets Management Branch (address above) written comments regarding the draft guidances. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified by the title of the respective draft guidance and with the docket number found in brackets in the heading of this document. The two draft guidance documents and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in revising the draft guidance documents.

Dated: March 15, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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Health Resources and Services Administration

Special Project Grants and Cooperative Agreements; Maternal and Child Health Services; Federal Set-Aside Program; Comprehensive Hemophilia Centers, Genetic Services, and Maternal and Child Health Improvement Projects

AGENCY: Health Resources and Services Administration (HRSA), PHS.

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that applications will be accepted for fiscal year (FY) 1996 funds for grants and cooperative agreements for the following activities: Maternal and Child Health (MCH) Special Projects of Regional and National Significance (SPRANS), including comprehensive hemophilia diagnostic and treatment centers; genetic disease testing, counseling and information services; and special MCH improvement projects (MCHIP) which contribute to the health of mothers, children, and children with special health care needs (CSHCN). All awards will be made under the program authority of section 502(a) of the Social Security Act, the MCH Federal Set-Aside Program. A revised regulation implementing the Federal Set-Aside Program (42 CFR part 51a) was published in the July 19, 1994, issue of the Federal Register at 59 FR 36703. Within the HRSA, SPRANS grants are administered by the Maternal and Child Health Bureau (MCHB). Awards are made for grant periods which generally run from 1 up to 5 years in duration. Grants for SPRANS research and training are being announced in a separate notice.

This program announcement is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for the MCH Federal Set-Aside Program, the amount

of available funding for this specific grant program cannot be estimated.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The MCH Block Grant Federal Set-Aside Program addresses issues related to the Healthy People 2000 objectives of improving maternal, infant, child and adolescent health and developing service systems for children with special health care needs. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office Washington, DC 20402-9325 (telephone: 202 783-3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, 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.

ADDRESSES: Grant applications for MCH SPRANS hemophilia, genetics, and MCHIP grants must be obtained from and submitted to: Chief, Grants Management Branch, Office of Operations and Management, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18-12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-1440. Applicants will use revised PHS form #5161-1, approved by the Office of Management and Budget (OMB) under control number 0937-0189. You must obtain application materials in the mail. Written requests should specify the category or categories of activities for which an application is requested so that the appropriate materials may be provided.

Federal Register notices and application guidance for MCHB programs are available on the World Wide Web via the Internet at address: <http://www.os.dhhs.gov/hrsa/mchb>. Click on the file name you want to download to your computer. It will be saved as a self-extracting (Macintosh or Wordperfect 5.1 file). To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a Wordperfect 5.1 file. If you have difficulty accessing the

MCHB Home Page via the Internet and need technical assistance, please contact Linda L. Schneider at 301-443-0767 or "lschneider@hrsa.ssw.dhhs.gov".

DATES: Potential applicants are invited to request application packages for the specific program category in which they are interested, and to submit their applications for funding consideration. Deadlines for receipt of applications differ for the several categories of grants. These deadlines may be found in Section 5, below, for each category covered by this notice.

Applications will be considered to have met the deadline if they are either: (1) Received on or before the deadline date, or (2) postmarked on or before the deadline date and received in time for orderly processing. Applicants should request a legibly dated receipt from a commercial carrier or the U.S. Postal Service, or obtain a legibly dated U.S. Postal Service postmark. Private metered postmarks will not be accepted as proof of timely mailing. Late applications or those sent to an address other than specified in the **ADDRESS** section will be returned to the applicant.

FOR FURTHER INFORMATION CONTACT:

Requests for technical or programmatic information should be directed to the contact persons identified below for each category covered by this notice. Requests for information concerning business management issues should be directed to: Acting Grants Management Officer (GMO), MCHB, at the address specified in the **ADDRESS** section.

SUPPLEMENTARY INFORMATION: To facilitate the use of this announcement, information in this section has been organized, as outlined in the Table of Contents below, into a discussion of: Program Background, Special Concerns, Evaluation Protocol, Project Review and Funding, SPRANS Project Grants, Public Comment, Eligible Applicants, and Public Health System Reporting Requirements. In addition, for each research and training funding category or subcategory, information is presented under the following headings:

- Application Deadline.
- Purpose.
- Priorities.
- Special Eligibility Considerations.
- Project Period.
- Contact.

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1. Program Background and Objectives

Under Section 502 of the Social Security Act, as amended by the Omnibus Budget Reconciliation Act (OBRA) of 1989, 12.75 percent of amounts appropriated for the MCH Block Grant in excess of \$600 million are set aside by the Secretary of Health and Human Services (HHS) for special Community Integrated Service Systems projects under Section 501(a)(3) of the Act. Of the remainder of the total appropriation, 15 percent of the funds are to be retained by the Secretary to support (through grants, contracts, or otherwise) special projects of regional and national significance, research, and training with respect to maternal and child health and children with special health care needs (including early intervention training and services development); for genetic disease testing, counseling, and information development and dissemination programs; for grants (including funding for comprehensive hemophilia diagnostic treatment centers) relating to hemophilia without regard to age; and for the screening of newborns for sickle cell anemia, and other genetic disorders and follow-up services. The MCH SPRANS set-aside was established in 1981. Support for projects covered by this announcement will come from the SPRANS set-aside. Applications for FY 1996 funds for MCH research and training grants are being solicited separately from other SPRANS grants this year in order to reduce confusion to potential applicants from

announcement of grants in very large numbers of SPRANS categories and subcategories.

2. Special Concerns

In its administration of the MCH Services Block Grant, the MCHB places special emphasis on improving service delivery to women and children from racial and ethnic minority populations who have had limited access to accessible care. This means that SPRANS projects are expected to serve and appropriately involve in project activities individuals from the populations to be served, unless there are compelling programmatic or other justifications for not doing so. The MCHB's intent is to ensure that project interventions are responsive to the cultural and linguistic needs of special populations, that services are accessible to consumers, and that the broadest possible representation of culturally distinct and historically underrepresented groups is supported through programs and projects sponsored by the MCHB. This same special emphasis applies to improving service delivery to children with special health care needs.

In keeping with the goals of advancing the development of human potential, strengthening the Nation's capacity to provide high quality education by broadening participation in MCHB programs of institutions that may have perspectives uniquely reflecting the Nation's cultural and linguistic diversity, and increasing opportunities for all Americans to participate in and benefit from Federal public health programs, HRSA will place a funding priority on projects from Historically Black Colleges and Universities (HBCU) or Hispanic Serving Institutions (HSI) in all categories and subcategories in this notice for which applications from academic institutions are encouraged. This is in conformity with the Federal Government's policies in support of White House Initiatives on Historically Black Colleges and Universities (Executive Order 12876) and Educational Excellence for Hispanic Americans (Executive Order 12900). An approved proposal from a HBCU or HSI will receive a 0.5 point favorable adjustment of the priority score in a 4 point range before funding decisions are made.

3. Evaluation Protocol

With the exception of SPRANS hemophilia projects—which have an alternative assessment mechanism in place—an MCH discretionary grant project, including a SPRANS, is

expected to incorporate a carefully designed and well planned evaluation protocol capable of demonstrating and documenting measurable progress toward achieving the project's stated goals. The protocol should be based on a clear rationale relating the grant activities, the project goals, and the evaluation measures. Wherever possible, the measurements of progress toward goals should focus on health outcome indicators, rather than on intermediate measures such as process or outputs. A project lacking a complete and well-conceived evaluation protocol as part of the planned activities will not be funded.

4. Project Review and Funding

Within the limit of funds determined by the Secretary to be available for the activities described in this announcement, the Secretary will review applications for funds under the specific project categories in section 4, below, as competing applications and may award Federal funding for projects which will, in her judgment, best promote the purpose of title V of the Social Security Act, with special emphasis on improving service delivery to women and children from culturally distinct populations; best address achievement of Healthy Children 2000 objectives related to maternal, infant, child and adolescent health and service systems for children at risk of chronic and disabling conditions; and otherwise best promote improvements in maternal and child health.

4.1 Criteria for Review

The criteria which follow are used, as pertinent, to review and evaluate applications for awards under all SPRANS grants and cooperative agreement project categories announced in this notice. Further guidance in this regard is supplied in application guidance materials, which may specify other criteria.

- The quality of the project plan or methodology.
- The need for the research or training.
- The extent to which the project will contribute to the advancement of maternal and child health and/or improvement of the health of children with special health care needs.
- The extent to which the project is responsive to policy concerns applicable to MCH grants and to program objectives, requirements, priorities and/or review criteria for specific project categories, as published in program announcements or guidance materials.
- The extent to which the estimated cost to the Government of the project

is reasonable, considering the anticipated results.

- 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.
- The extent to which, insofar as practicable, the proposed activities, if well executed, are capable of attaining project objectives.
- The strength of the project's plans for evaluation.
- The extent to which the project will be integrated with the administration of the MCH Block Grant, State primary care plans, public health, and prevention programs, and other related programs in the respective State(s).
- The extent to which the application is responsive to the special concerns and program priorities specified in this notice.

4.2 Funding of Approved Applications

Final funding decisions for SPRANS grants are the responsibility of the Director, MCHB. In considering scores for the ranking of approved applications for funding, preferences may be exercised for groups of applications; for example, new projects may be funded ahead of competing continuations, or vice versa. Within any category of approved projects, the score of an individual project may be favorably adjusted, as noted in the notice or in guidance for that category, if the project addresses specific identified priorities. In addition, special consideration in assigning scores may be given by reviewers to individual applications that address areas identified in this notice as special concerns.

5. Special Projects of Regional and National Significance

Three categories of SPRANS grants are discussed below: Comprehensive Hemophilia Diagnostic and Treatment Centers; Genetic Disease Testing, Counseling and Information; and Maternal and Child Health Improvement Projects.

5.1 Grants

Three major categories of SPRANS grants are discussed below: Comprehensive Hemophilia Diagnostic and Treatment Centers; Genetic Disease Testing, Counseling and Information; and Maternal and Child Health Improvement Projects (in 5 sub-categories):

5.1.1. Comprehensive Hemophilia Diagnostic and Treatment Centers

- Application Deadline: June 17, 1996.
 - Purpose: To provide comprehensive hemophilia diagnostic and treatment services to individuals with hemophilia and other congenital bleeding disorders through a regional network of approximately 140 comprehensive hemophilia diagnostic and treatment centers and for regional coordination.
 - Priorities: The following overall program goals are priorities; to be eligible for consideration, proposals must address all of these:
 - Access to comprehensive care for hemophilia and HIV as described in "Standards and Criteria for the Care of Persons with Congenital Bleeding Disorders" as published by the National Hemophilia Foundation (NHF).
 - Fostering development of comprehensive care systems that provide culturally sensitive, family-centered care, coordinated through a regional system of hemophilia diagnostic and treatment centers.
 - Outreach and increased access to comprehensive care, especially to the underserved and minorities.
 - Emphasis on prevention to reduce complications and morbidity associated with hemophilia.
 - Provision of services to women with congenital bleeding disorders.
 - Collaboration and coordination of services with State Title V Maternal and Child Health programs; Ryan White Titles I, II, and III; community based organizations; State and local health agencies; Ryan White Title IV Pediatric HIV projects funded by the MCHB; and education and peer support activities of the NHF, such as Men's Advocacy Network of NHF (MANN), Women's Outreach Network of NHF (WONN) and Chapter Outreach Development Program (CODP); and with the Centers for Disease Control and Prevention (CDC) regarding the provision of HIV prevention, risk reduction, and counseling services, especially those targeted to adolescents and their sexual partners.
 - Evidence of formal patient choice and grievance policies and procedures.
- Preference for funding will be given to existing MCHB-supported comprehensive hemophilia diagnostic and treatment centers that have demonstrated high performance in development and coordination of regional services.
- Project Period: The project period is 3 years.

- Contact: For programmatic or technical information, contact Patrick McGuckin, on (301) 443-9051.

5.1.2. Genetic Disease Testing, Counseling and Information

- Application deadline: April 29, 1996.
 - Purpose: To support projects that demonstrate increased access to effective genetic information, education, testing, and counseling services.
 - Priorities: Applicants are invited to submit proposals to broaden access to genetic services through the following:
 - A council of regional networks for genetic services. To coordinate activities and facilitate collaboration of ten regional genetic services networks supported by MCHB, and to address issues of genetic services in public health programs at the national level.
 - Four regional genetic services networks. To develop and maintain infrastructures for genetic services in the Midwest/Great Plains, Mid-Atlantic, New England, and Southeast regions of the United States.
 - An alliance of genetic support groups. To maintain a national coalition of genetics support groups, consumers, and professionals to improve responsiveness of genetic services to concerns of individuals and families affected by genetic disorders.
- Preference for funding will be given to existing MCHB-supported comprehensive genetic projects that have demonstrated high performance in fulfilling the above priorities.

- Project Period: Project periods are up to 3 years.
- Contact: For programmatic or technical information, contact Jane S. Lin-Fu, M.D., telephone 301/443-1080.

5.1.3. Maternal and Child Health Improvement Projects

Maternal and Child Health Improvement Projects (MCHIP) are divided into five subcategories: State Systems Development Initiative; Transition Services in Adolescent Health; Universal Newborn Hearing Screening; Data Utilization and Enhancement; and Healthy Tomorrows Partnerships for Children

5.1.3.1. State Systems Development Initiative.

Application Deadline: July 15, 1996.
 Purpose: To assist State Agency Maternal and Child Health and Children with Special Health Care Need programs in the development of a State and community infrastructure that results in comprehensive, community-based systems of care for all children and their

families. Projects must: (1) support systems development activities identified in the Title V MCH Block Grant application; (2) collaborate with CISS, Healthy Start, and the Primary Care Cooperative Agreement; (3) collaborate with other system development initiatives, such as, mental health and education; (4) build on systems already in place; (5) and make an effort to sustain systems development activities in the Title V agency.

- Priorities: Priority for funding will be given to projects in the following areas:
- Establishing an integrated data management system which meets user needs at the local, State, and national levels and is electronically accessible.
 - Supporting community-level planning for establishing priorities, policies, and strategies for systems development.
 - Improving collaborative partnerships for integrating health services.
 - Initiating collaborative partnerships for integrating health with other services, e.g., education, mental health, and social services.
 - Promoting service systems that are family-centered and culturally competent.
 - Developing a mechanism for assuring quality performance and utilization of community systems.
 - Strengthening the skills, knowledge, and ability of state and community leaders to develop comprehensive community systems of care.

Special Eligibility Considerations: Eligibility for funding is limited to the Title V agencies in the 50 States and 9 Jurisdictions.

Project Period: Three years.

Contact: Kay K. Guirl, R.N., M.N., Senior Public Health Analyst, Division of Services for Children with Special Health Needs, 301 443-2350.

5.1.3.2. Transition Services in Adolescent Health.

- Application Deadline: May 15, 1996.
- Purpose: To fund two categories of SPRANS projects which support ongoing efforts to develop comprehensive, culturally competent, community-based, family-centered, coordinated care systems for adolescents with special health care needs and their families. The funds are intended to help these adolescents achieve a successful transition to community-based, comprehensive care and to maximize potential for employment. The MCHB has identified the need for public and private partnerships to improve the coordination of services to assist and

support adolescents with disabilities. These efforts are based, in part, on the work of the Federal SSI/CSHCN Workgroup, a collaborative effort of the MCHB, the Social Security Administration (SSA), and State Title V CSHCN Programs, which has identified barriers faced by adolescents with special health needs; and the National Commission on Childhood Disability, which, in its October, 1995, Report to Congress, identified changes needed in the SSI Program to more effectively promote self sufficiency of SSI child beneficiaries.

Another excellent example of ongoing collaboration, the CHOICES Project is a public/private partnership jointly funded by the MCHB and the Shriners Hospitals. CHOICES has strengthened cooperation between Title V CSNCN programs, Shriners Hospitals, and Vocational Rehabilitation programs and maximized services available to adolescents with disabilities. The MCHB is seeking to build on the past efforts of CHOICES, to strengthen systems of care for adolescents and preadolescents with special health needs and encourage them to grow, develop and make a successful transition to comprehensive care, work and self sufficiency. Utilizing the resources of a broad spectrum of health and social services providers, vocational training and rehabilitation agencies, education and private employers, the initiative will: (1) Identify and increase the understanding of the needs and special problems of adolescents with disabilities in making successful transitions to adult care, to be "healthy and ready to work" and to achieve self sufficiency; (2) foster the development of public and private partnerships and collaborative relationships that will maximize the availability of and access to comprehensive, community-based, coordinated care systems for adolescents with special health needs and their families; and (3) improve the ability of adolescents with disabilities to lead productive lives and maximize financial independence.

- **Priorities/Funding Categories:** Applications are being accepted for two categories of projects in FY 1996. Applications which do not fall within these program categories will not be considered.

—The Priority 1 funding category will support community-based planning and initial development grants to strengthen community-based systems that help adolescents with disabilities make successful transitions to self sufficiency and work. The emphasis of this category is on support for

community level infrastructures of agencies, providers, community organizations, business and families. Projects will focus on needs assessment and local capacity-building, identifying and making maximum use of all available public and private resources for reaching and providing services to the target population. Services to transition adolescents from child-centered to adult-based care are expected to include primary, preventive, and specialty care that also addresses psychosocial needs. Projects must involve targeted adolescents and their families in needs assessment, as well as ongoing project planning and development. Funding will support local capacity building for planning, coordination of services, and care and financing systems development. Collaboration must be evident with key public programs within the community responsible for serving adolescents with special needs and disabilities funded under Title V Maternal and Child Health programs, vocational rehabilitation, education, mental health, social services agencies, and the State's SSI Action Plan.

—The Priority 2 funding category will expand already established regional and/or national efforts to support adolescents in making successful transitions from hospital to ambulatory care, to be "healthy and ready to work" and to achieve independence. Priority 2 projects will have the same general goals as those defined in Priority 1; however Priority 2 applicants must have already completed planning and initial development and have an existing infrastructure to achieve project goals and objectives. This infrastructure must, at a minimum, include selected State Title V CSHCN programs, Shriners Hospitals, and Vocational Rehabilitation programs. Applicants must represent a public/private partnership of Title V and a national hospital network which serves significant numbers of adolescents with disabilities. In addressing the goal of preparing adolescents to make transitions to adult comprehensive care and independent living, the project must involve community resources, including Vocational Rehabilitation, education, and employers in order to identify appropriate work opportunities and assure that adolescents have ongoing comprehensive and coordinated health care coverage.

- **Special Eligibility Considerations:** In keeping with the September 15, 1995, report of the U.S. Senate Appropriations Committee (S. Rep. 104-145), which urged continued MCHB support for the CHOICES Project, special preference for Priority 2 grants will be given to projects of similar scope and organization.

- **Project Period:** One to two year awards for Priority 1 projects; one to three years for Priority 2 projects.

- **Contact:** For programmatic or technical information, contact Beth D. Roy, telephone 301 443-2370. A pre-application conference call will be held on Thursday, April 18, at 2:00 p.m., EST. Persons interested in participating should send a letter of interest, including a brief description of their proposal and any issues they wish to have addressed during the call, by Friday, April 5, to Beth Roy, Room 18A-27, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

5.1.3.3. *Universal Newborn Hearing Screening.*

- **Application Deadline:** May 17, 1996.

- **Purpose:** To promote the establishment of statewide universal newborn hearing screening programs in the United States through a national network which (a) increases awareness of the feasibility of newborn hearing screening, (b) provides technical assistance on program establishment, maintenance, and coordination, and (c) maintains and analyzes data to monitor and evaluate the impact of universal newborn hearing screening programs. This priority responds to the Healthy People 2000 objective (17.16) which calls for the reduction in the average age at which children with significant hearing impairment are identified to no more than 12 months.

- **Priorities:** Priority for funding will be given to those applications which address the following factors:

—Coordination of screening programs emphasizing linkages between hospital screening programs, pediatricians, audiologists, state agencies, and community services providers.

—Sustainability beyond the grant period emphasizing utilization of local funding to establish and institutionalize programs as part of the ongoing provision of health care services.

—Ongoing support and technical assistance for emerging programs utilizing valid, cost effective, and feasible strategies and instrumentation for the conduct of universal hearing screening.

—Impact of early screening, emphasizing outcome evaluation

which includes both quantitative and qualitative data on identification, intervention, cost, and developmental outcomes for young children.

- Project Period: The project period is four years.

- Contact: For programmatic or technical information, contact Bonnie Strickland, Ph.D., 301/443-1080.

4.1.3.4. Data Utilization and Enhancement.

- Application Deadline: June 17, 1996.

- Purpose: To enhance the use of information and information technologies within State and local MCH/CSHCN agencies and within the MCH community in the development of policies, programs and evaluation of services to improve the health and well being of mothers and all children as outlined in the "MCH Strategy Statement: Data Systems and Enhancement." Activities in this initiative may include:

- Development of retrievable and usable information and model data systems. The systems will be used in the collection, management, and analysis of data to facilitate needs assessment, planning, program implementation, monitoring, and evaluation of the health status of mothers and children and the delivery of comprehensive health care to that population.

- Linkage of and/or improvement of access to information among various service and data systems. These may include administrative, clinical, educational, communities and population information.

- Analysis of economic cost, benefits and effectiveness of services and systems on the well being of the MCH community, particularly the high risk and underserved portions of the population, including a compilation of service cost impacts related to health outcomes, cost benefit analysis of major MCH services, and dissemination of economic information to the MCH community.

Work products may take a variety of forms, such as papers, models, software, information services, stipends, and reports. Work products will be directed to the MCH community, including all mothers and children, and the service and system providers integral to providing them with comprehensive, family centered, culturally competent, community services.

- Priorities: Proposals in this MCHIP subcategory are invited in the following program areas:

- Development of model information systems with data that can be

retrieved, integrated, and used by others at national and State levels.

- Enhancement of information collection and analysis capabilities of national, State and local health agencies using the models developed, training, and peer consultation.

- Collection, management, and analysis of data, and development and application of analytic and information management techniques focusing on national MCH issues.

- Networking, coordination, and integration of existing and proposed resources and data information technologies and analysis systems developed by other States or organizations.

- Increasing national, State and local analytical and information system capacity to respond to and implement changes in the organization of health care resources.

- Dissemination of relevant programmatic and population information and developed models to enhance access and utility for the MCH populations.

- Provision of direction and incentives to individuals in carrying out the purpose of this initiative through partnerships with educational institutions and State and local MCH agencies.

- Monitoring and assessing information and information technology requirements parallel to organizational changes in delivery of health care services to all mother and children.

- Grants/Amounts: Up to 3 years, with declining Federal funding and escalating local funding.

- Contact: For programmatic or technical information, contact Russ Scarato, telephone: 301 443-8041.

5.1.3.5. Healthy Tomorrows Partnerships for Children.

- Application Deadline: May 13, 1996.

- Purpose: To support projects for mothers and children that improve access to health services and utilize preventive strategies. The initiative encourages additional support from the private sector and from foundations to form community-based partnerships to coordinate health resources for pregnant women, infants and children.

- Priorities: Proposals in this MCHIP category are invited in the following program areas:

- Local initiatives that are community-based, family-centered, comprehensive and culturally relevant and improve access to health services for infants, children, adolescents, or CSHCN.

- Initiatives which show evidence of a capability to meet cost participation goals by securing funds for the second and sequential years of the project.

- Special Eligibility Considerations:

In the interest of equitable geographic distribution, special consideration for funding will be given to projects from States without a currently funded project in this category. These States are cited in the application guidance.

- Project Period: Five years.

- Contact: For programmatic or technical information, contact Latricia Robertson, M.S.N., M.P.H., telephone: 301 443-8041.

5.2. Cooperative Agreements

Cooperative agreements will be awarded in four categories: Maternal and Child Health Providers Partnership; Partnership for Information and Communication; Fetal/Infant Mortality Review Program Support Center; and Partnership for Adolescent Health.

There will be substantial Federal programmatic involvement in these cooperative agreements. This means that after award, awarding office staff provide technical assistance and guidance to, or coordinate and participate in, certain programmatic activities of award recipients beyond their normal stewardship responsibilities in the administration of grants. Federal involvement may include, but is not limited to, planning, guidance, coordination and participation in programmatic activities. Periodic meetings, conferences, and/or communications with the award recipient are held to review mutually agreed upon goals and objectives and to assess progress. Additional details on the scope of Federal programmatic involvement in cooperative agreements, consistent with HRSA grants administration policy, will be included in the application guidance for these cooperative agreements.

5.2.1. Maternal and Child Health Providers Partnership

- Application Deadline: June 1, 1996.

- Purpose: To support activities which improve access and the delivery of maternal and child health services through governmental and professional partnerships. Specifically, the program is designed to promote problem-solving approaches which enhance community and provider participation. This provider partnership will encourage private sector and other support for improved coordination of and access to health resources at the community-level for pregnant women, infants and children.

Any national membership organization able to demonstrate that it represents a group(s) of providers of pediatric services will be considered for funding.

Specific program requirements include:

- Analysis of the obstacles (issues and contributing factors) to provider participation in the delivery of maternal and child health services to low-income pregnant women and children, as well as involvement in problem solving at the community level.
- Development of strategies to improve maternal and child health status and systems through collaboration with the Federal MCHB which promote problem solving at the community level; encourage provider participation; and encourage private sector and other support for improved coordination of and access to health resources at the community level.
- Dissemination and effective communication of concerns and information pertaining to the issues and strategies employed to their members and other national organizations.
 - Project Period: Up to 5 years.
 - Contact: For programmatic or technical information, contact Latricia Robertson, M.S.N., M.P.H., telephone: 301-443-8041.

5.2.2. Partnership for Information and Communication (PIC)

- Application Deadline: June 15, 1996.
- Purpose: To facilitate dissemination of new maternal and child health-related information to policy and decision makers in a format most useful to them and provide those individuals with a means of communicating issues directly to each other and to MCHB. This is a continuous Bureau activity with a single priority—to enhance communication between the MCHB and governmental, professional and private organizations representing leaders and policy makers concerned with issues related to maternal and child health. Organizations currently receiving support as part of this cooperative agreement represent State governors and their staffs; State Title V programs; State legislators; private business, particularly self-insured businesses; philanthropic organizations; and parent organizations, as well as national membership organizations representing groups or constituencies listed below.

To ensure continuity, membership for the organizations participating in PIC is rotated so that not all project periods

coincide. For this year, only national membership organizations representing the following groups will be considered for funding:

- County health policymakers.
- Municipal health policymakers.
 - Project Period: Up to 5 years.
 - Contact: For programmatic or technical information, contact David Heppel, M.D., telephone: 301-443-2250.

5.2.3. Fetal/Infant Mortality Review Program Support Center

- Application Deadline: June 14, 1996.
- Purpose: To provide technical support to States and communities as they develop and implement community-based fetal/infant mortality review process. Fetal/Infant Mortality Review (F/IMR) is a process that identifies, through use of a community multidisciplinary team, community health care system, economic and social factors that may have contributed to an infant death. These findings are then used by the community to address the identified contributing factors and to promote local program development.

The Center will be responsible for working with the MCHB to promote the F/IMR process, provide assistance in setting up the process, share pertinent information among communities and States, develop refinements and new approaches to the F/IMR process to make it more responsive and efficient, and expand the use of this problem-solving to other mortality and morbidity events impacting the MCH population.

- Project Period: Up to five years.
- Contact: For programmatic or technical information, contact David Heppel, M.D., telephone: 301-443-2250.

5.2.4. Partnership for Adolescent Health

- Application Deadline: June 14, 1996.
- Purpose: To collaborate with membership organizations having an historic interest in adolescent health in seeking policy guidance from and providing programmatic information to their memberships. This cooperative agreement stems from Congress's mandate to the Department, in section 1708 of the Public Health Service Act, to create an Office of Adolescent Health (OAH). The functions of the OAH are delegated to the MCHB. Fulfilling the need for a focal point for adolescent health, the OAH is responsible for assisting private and other public organizations to develop a collaborative approach to planning, implementing, monitoring and evaluating national

programs to promote, improve and maintain the health status of pre-adolescents and adolescents.

Priorities: For purposes of this competition, only membership organizations representing the following disciplines will be considered for funding:

- Law.
- Social Work.
- Psychology.
- Medicine.

Future competitions will be focused on other professional disciplines.

Project Period: Up to 5 years.
Contact: For programmatic or technical information contact Juanita C. Evans, LCSW, telephone: 301 443-4026.

6. Public Comment

The categories, priorities, special considerations and preferences described above are not being proposed for public comment this year. In July 1993, following publication of the Department's Notice of Proposed Rulemaking to revise the MCH special project grant regulations at 42 CFR part 51a, the public was invited for a 60-day period to submit comments regarding all aspects of the SPRANS application and review process. In responding to those comments, the Department noted the practical limits on Secretarial discretion in establishing SPRANS categories and priorities owing to the extensive prescription in both the statute and annual Congressional directives.

Comments on this SPRANS notice which members of the public wish to make are welcome at any time and may be submitted to: Director, MCHB, at the address listed in the **ADDRESS** section. Suggestions will be considered when priorities are developed for the next solicitation.

7. Eligible Applicants

Any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450b), is eligible to apply for grants or cooperative agreements for project categories covered in this announcement.

8. Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937-0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant

applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

- (a) A copy of the face page of the application (SF 424).
- (b) A summary of the project (PHSIS), not to exceed one page, which provides:
 - (1) A description of the population to be served.
 - (2) A summary of the services to be provided.
 - (3) A description of the coordination planned with the appropriate State and local health agencies.

The project abstract may be used in lieu of the one-page PHSIS, if the applicant is required to submit a PHSIS.

9. Executive Order 12372

The MCH Federal set-aside program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

The OMB Catalog of Federal Domestic Assistance number is 93.110.

Dated: March 19, 1996.

Ciro V. Sumaya,
Administrator.

[FR Doc. 96-7106 Filed 3-22-96; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application.

The following applicant has applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

PRT-812539

Applicant: Dr. Rolf O. Peterson, Michigan Technological University, Houghton, Michigan.

The applicant requests a permit to take (capture, handle and release) gray wolves (*Canis lupus lycaon*) in Isle Royale National Park, Michigan, for the purpose of enhancement of survival of the species through scientific research.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Division of Endangered Species, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with this application are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, division of Endangered Species, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056. Telephone: (612/725-3536 x250); FAX: (612/725-3526).

Dated: March 19, 1996.

Mamie A. Parker,

Acting Assistant Regional Director, Ecological Services, Region 3, Fish and Wildlife Service, Fort Snelling, Minnesota.

[FR Doc. 96-7136 Filed 3-22-96; 8:45 am]

BILLING CODE 4310-55-M

Endangered and Threatened Species Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application.

The following applicants have applied for amendments to their permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

PRT-809630

Applicant: Dr. Allen Kurta, Eastern Michigan University, Ypsilanti, Michigan.

The applicant requests an amendment to his scientific take permit for Indiana Bats (*Myotis sodalis*) to add Indiana, Ohio, and Illinois to the scope of permitted activities. Take activities are currently authorized in Michigan and include capture, handling, radio-tagging, and release of specimens.

PRT-809227

Applicant: 3D/Environmental, Cincinnati, Ohio, Dr. Virgil Brack, President.

Applicant requests an amendment to their scientific take permit for Indiana Bats (*Myotis sodalis*) and Gray Bats (*Myotis grisescens*) to include the following states within the scope of permitted activities: Alabama, Arkansas, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.

Written data or comments on either of these amendment requests should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Division of Endangered Species, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Division of Endangered Species, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056. Telephone: (612/725-3536 x250); FAX: (612/725-3526).

Dated: March 19, 1996.

Mamie A. Parker,

Acting Assistant Regional Director, Ecological Services, Region 3, Fish and Wildlife Service, Fort Snelling, Minnesota.

[FR Doc. 96-7138 Filed 3-22-96; 8:45 am]

BILLING CODE 4310-5-M

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior

ACTION: Notice of Receipt of Application for Permit.

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*):

PRT-812350

Applicant: Mr. Phillip Sacco, CH2M HILL, Atlanta, Georgia.

The applicant requests a permit to take (capture for presence/absence survey) the endangered Indiana bat, *Myotis sodalis*, and gray bat, *Myotis grisescens*, at a proposed landfill expansion site, Sullivan County, Tennessee for the purpose of enhancement of survival of the species.

PRT-812346

Applicant: Ms. Kimberly M. Elliott, Antioch, Tennessee.

The applicant requests a permit to take (capture, mark, and release) the endangered Nashville crayfish, *Orconectes shoupi*, in Davidson County, Tennessee, for the purpose of enhancement of survival of the species.