

SEC. 2504. SCREENINGS, REFERRALS, AND EDUCATION REGARDING LEAD POISONING.

Section 317A(1)(1) of the Public Health Service Act (42 U.S.C. 247b–1(1)(1)) is amended by striking “1994” and all that follows and inserting “1994 through 2005.”.

TITLE XXVI—SCREENING FOR HERITABLE DISORDERS

SEC. 2601. PROGRAM TO IMPROVE THE ABILITY OF STATES TO PROVIDE NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

Part A of title XI of the Public Health Service Act, as amended by section 2301 of this Act, is amended by adding at the end the following:

“SEC. 1109. IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

“(a) **IN GENERAL.**—The Secretary shall award grants to eligible entities to enhance, improve or expand the ability of State and local public health agencies to provide screening, counseling or health care services to newborns and children having or at risk for heritable disorders.

“(b) **USE OF FUNDS.**—Amounts provided under a grant awarded under subsection (a) shall be used to—

“(1) establish, expand, or improve systems or programs to provide screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

“(2) establish, expand, or improve programs or services to reduce mortality or morbidity from heritable disorders;

“(3) establish, expand, or improve systems or programs to provide information and counseling on available therapies for newborns and children with heritable disorders;

“(4) improve the access of medically underserved populations to screening, counseling, testing and specialty services for newborns and children having or at risk for heritable disorders; or

“(5) conduct such other activities as may be necessary to enable newborns and children having or at risk for heritable disorders to receive screening, counseling, testing or specialty services, regardless of income, race, color, religion, sex, national origin, age, or disability.

“(c) **ELIGIBLE ENTITIES.**—To be eligible to receive a grant under subsection (a) an entity shall—

“(1) be a State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States; and

“(2) prepare and submit to the Secretary an application that includes—

“(A) a plan to use amounts awarded under the grant to meet specific health status goals and objectives relative to heritable disorders, including attention to needs of medically underserved populations;

“(B) a plan for the collection of outcome data or other methods of evaluating the degree to which amounts

awarded under this grant will be used to achieve the goals and objectives identified under subparagraph (A);

“(C) a plan for monitoring and ensuring the quality of services provided under the grant;

“(D) an assurance that amounts awarded under the grant will be used only to implement the approved plan for the State;

“(E) an assurance that the provision of services under the plan is coordinated with services provided under programs implemented in the State under title V, XVIII, XIX, XX, or XXI of the Social Security Act (subject to Federal regulations applicable to such programs) so that the coverage of services under such titles is not substantially diminished by the use of granted funds; and

“(F) such other information determined by the Secretary to be necessary.

“(d) LIMITATION.—An eligible entity may not use amounts received under this section to—

“(1) provide cash payments to or on behalf of affected individuals;

“(2) provide inpatient services;

“(3) purchase land or make capital improvements to property; or

“(4) provide for proprietary research or training.

“(e) VOLUNTARY PARTICIPATION.—The participation by any individual in any program or portion thereof established or operated with funds received under this section shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, another Federal or State program.

“(f) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities of the type described in this section.

“(g) PUBLICATION.—

“(1) IN GENERAL.—An application submitted under subsection (c)(2) shall be made public by the State in such a manner as to facilitate comment from any person, including through hearings and other methods used to facilitate comments from the public.

“(2) COMMENTS.—Comments received by the State after the publication described in paragraph (1) shall be addressed in the application submitted under subsection (c)(2).

“(h) TECHNICAL ASSISTANCE.—The Secretary shall provide to entities receiving grants under subsection (a) such technical assistance as may be necessary to ensure the quality of programs conducted under this section.

“(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

“SEC. 1110. EVALUATING THE EFFECTIVENESS OF NEWBORN AND CHILD SCREENING PROGRAMS.

“(a) IN GENERAL.—The Secretary shall award grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness of screening, counseling or health care

services in reducing the morbidity and mortality caused by heritable disorders in newborns and children.

“(b) **DEMONSTRATION PROGRAMS.**—A demonstration program conducted under a grant under this section shall be designed to evaluate and assess, within the jurisdiction of the entity receiving such grant—

“(1) the effectiveness of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders in reducing the morbidity and mortality associated with such disorders;

“(2) the effectiveness of screening, counseling, testing or specialty services in accurately and reliably diagnosing heritable disorders in newborns and children; or

“(3) the availability of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders.

“(c) **ELIGIBLE ENTITIES.**—To be eligible to receive a grant under subsection (a) an entity shall be a State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States.

“SEC. 1111. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

“(a) **ESTABLISHMENT.**—The Secretary shall establish an advisory committee to be known as the ‘Advisory Committee on Heritable Disorders in Newborns and Children’ (referred to in this section as the ‘Advisory Committee’).

“(b) **DUTIES.**—The Advisory Committee shall—

“(1) provide advice and recommendations to the Secretary concerning grants and projects awarded or funded under section 1109;

“(2) provide technical information to the Secretary for the development of policies and priorities for the administration of grants under section 1109; and

“(3) provide such recommendations, advice or information as may be necessary to enhance, expand or improve the ability of the Secretary to reduce the mortality or morbidity from heritable disorders.

“(c) **MEMBERSHIP.**—

“(1) **IN GENERAL.**—The Secretary shall appoint not to exceed 15 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

“(2) **REQUIRED MEMBERS.**—The Secretary shall appoint to the Advisory Committee under paragraph (1)—

“(A) the Administrator of the Health Resources and Services Administration;

“(B) the Director of the Centers for Disease Control and Prevention;

“(C) the Director of the National Institutes of Health;

“(D) the Director of the Agency for Healthcare Research and Quality;

“(E) medical, technical, or scientific professionals with special expertise in heritable disorders, or in providing screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

“(F) members of the public having special expertise about or concern with heritable disorders; and

“(G) representatives from such Federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary, to fulfill the duties of the Advisory Committee, as established under subsection (b).”.

TITLE XXVII—PEDIATRIC RESEARCH PROTECTIONS

SEC. 2701. REQUIREMENT FOR ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED IN RESEARCH.

Notwithstanding any other provision of law, not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall require that all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services be in compliance with subpart D of part 46 of title 45, Code of Federal Regulations.

TITLE XXVIII—MISCELLANEOUS PROVISIONS

SEC. 2801. REPORT REGARDING RESEARCH ON RARE DISEASES IN CHILDREN.

Not later than 180 days after the date of the enactment of this Act, the Director of the National Institutes of Health shall submit to the Congress a report on—

(1) the activities that, during fiscal year 2000, were conducted and supported by such Institutes with respect to rare diseases in children, including Friedreich’s ataxia and Hutchinson-Gilford progeria syndrome; and

(2) the activities that are planned to be conducted and supported by such Institutes with respect to such diseases during the fiscal years 2001 through 2005.

SEC. 2802. STUDY ON METABOLIC DISORDERS.

(a) **IN GENERAL.**—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall, in consultation with relevant experts or through the Institute of Medicine, study issues related to treatment of PKU and other metabolic disorders for children, adolescents, and adults, and mechanisms to assure access to effective treatment, including special diets, for children and others with PKU and other metabolic disorders. Such mechanisms shall be evidence-based and reflect the best scientific knowledge regarding effective treatment and prevention of disease progression.

(b) **DISSEMINATION OF RESULTS.**—Upon completion of the study referred to in subsection (a), the Secretary shall disseminate and otherwise make available the results of the study to interested groups and organizations, including insurance commissioners, employers, private insurers, health care professionals, State and local public health agencies, and State agencies that carry out the Medicaid program under title XIX of the Social Security Act