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114TH CONGRESS
2D SESSION

H. R. 5479

To provide for programs under the Department of Health and Human Services to improve newborn screening, evaluation, and intervention for critical congenital heart defect.

IN THE HOUSE OF REPRESENTATIVES

JUNE 14, 2016

Ms. MCCOLLUM introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To provide for programs under the Department of Health and Human Services to improve newborn screening, evaluation, and intervention for critical congenital heart defect.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Screening Hearts in Newborns for Early Detection of Congenital Heart Defect Act'' or the ''SHINE Act''.

SEC. 2. PROGRAMS TO IMPROVE NEWBORN SCREENING, EVALUATION, AND INTERVENTION FOR CRITICAL CONGENITAL HEART DEFECT.

(a) STATEWIDE NEWBORN SCREENING PROGRAMS, EVALUATION AND INTERVENTION PROGRAMS AND INFORMATION SYSTEMS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall make awards of grants or cooperative agreements to States to—

(A) develop and improve, with respect to critical congenital heart defect, statewide newborn CCHD screening, evaluation, diagnosis, results reporting, data collection and surveillance, and intervention programs and systems; and

(B) assist in the recruitment, retention, education, and training of qualified personnel;

for the purposes described in paragraph (2).

(2) PURPOSES.—For purposes of paragraph (1), the purposes described in this paragraph are the following:

(A) To develop and monitor the efficacy of statewide programs and systems for CCHD screening of newborns, evaluate and diagnose newborns referred from screening programs, and provide for educational and medical inter-

ventions for newborns identified with critical congenital heart defect (and other health conditions associated with hypoxemia).

(B) To provide for early intervention, including—

(i) referral to and delivery of information and services, relating to CCHD screening, evaluation, and diagnosis, by entities and agencies, including clinical, community, consumer, and parent-based agencies and organizations; and

(ii) other programs mandated by part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 et seq.), which offer programs specifically designed to meet the unique needs of newborns with critical congenital heart defect and which establish and foster family-to-family support mechanisms critical in the first months after a newborn is identified with critical congenital heart defect.

(C) To collect data on statewide newborn CCHD screening and screening of secondary conditions and evaluation and intervention programs and systems that can be applied for

quality improvement, research, program evaluation, and policy development.

(D) To encourage the adoption by State agencies of models described in subparagraph (E).

(E) To provide for other activities, which may include the development of efficient models to ensure that newborns who are identified with critical congenital heart defect through screening receive follow-up by a qualified health care provider.

(b) CCHD INFORMATION AND SURVEILLANCE SYSTEMS AND APPLIED RESEARCH.—

(1) CENTERS FOR DISEASE CONTROL AND PREVENTION.—In accordance with the recommendations described in paragraph (5), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies to complement intramural programs and to conduct applied research related to newborn CCHD screening, evaluation and intervention programs, and data collection and information systems, such as—

(A) standardized procedures for data management and program effectiveness to ensure quality monitoring of newborn CCHD screening, evaluation, diagnosis, and intervention programs and systems;

(B) evaluation of the current capacity of existing population-based State surveillance and tracking to monitor the effectiveness of newborn CCHD screening to reduce infant mortality and morbidity;

(C) provision of technical assistance on data collection and management, including leveraging an electronic health record framework for critical congenital heart defect data and reporting;

(D) study of the costs and effectiveness of newborn CCHD screening and secondary targets and nontarget conditions associated with hypoxemia;

(E) evaluation and intervention programs and systems conducted by State-based programs in order to answer issues of importance to State and national policymakers;

(F) further study of the causes and risk factors for critical congenital heart defect;

(G) study of the effectiveness of newborn CCHDs screening, followup diagnostics, medical evaluations and intervention programs and systems by assessing the health, intellectual, and social developmental, cognitive, and neurodevelopmental status of such children as they grow and enter school age; and

(H) data reporting by State agencies to the Department of Health and Human Services regarding CCHD screening conducted as part of State-based birth defects monitoring and long-term follow up programs for the purpose of providing appropriate services.

(2) NATIONAL INSTITUTES OF HEALTH.—In accordance with the recommendations described in paragraph (5), the Director of the National Institutes of Health shall, for purposes of this section—

(A) conduct a program of research and development on the efficacy of new screening techniques and technology, including clinical studies of screening methods, follow-up diagnostic tools, and studies on efficacy of intervention and related research; and

(B) acting through the National Library of Medicine of the National Institutes of Health,

assist the Secretary with the development and deployment of expanded coding terminology for pulse oximetry screening for CCHD and follow-up diagnostic testing related to screening and integrating results into electronic medical records and as part of interoperability with public health information systems.

(3) HEALTH RESOURCES SERVICES ADMINISTRATION.—In accordance with the recommendations described in paragraph (5), the Administrator of the Health Resources and Services Administration shall, in coordination with the Director of the Centers for Disease Control and Prevention—

(A) guide the assessment and improvement of screening standards and infrastructure needed for the implementation of a public health approach to point of care screening for congenital heart defects; and

(B) coordinate and collaborate in assisting States to establish newborn CCHD screening and other secondary conditions associated with hypoxemia, evaluation, diagnosis, and intervention programs and systems under paragraph (1) and to develop a data collection system under paragraph (2).

(4) FDA CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.—In accordance with the recommendations described in paragraph (5), the Center for Devices and Radiological Health of the Food and Drug Administration shall provide guidance to health care providers, industry, and staff of the Food and Drug Administration on pulse oximeters and the unique role of pulse oximetry in screening neonatal patients.

(5) RECOMMENDATIONS.—The recommendations described in this paragraph are the following recommendations contained in the plan of action of the Interagency Coordinating Committee on Newborn and Child Screening established under section 114 of the Public Health Service Act (42 U.S.C. 300b–13):

(A) The recommendation for the Centers for Disease Control and Prevention to fund surveillance activities to monitor the CCHD link to infant mortality and other health outcomes.

(B) The recommendation for the National Institutes of Health to fund research activities to determine the relationships among the screening technology, diagnostic processes, care provided, and health outcomes of affected

newborns with CCHD as a result of prospective newborn screening.

(C) The recommendation for the Health Resources and Services Administration to guide the development of screening standards and infrastructure needed for the implementation of a public health approach to point of service screening for critical congenital cyanotic heart defect.

(D) The recommendation for the Health Resources and Services Administration to fund the development of, in collaboration with public health and health care professional organizations and families, appropriate education and training materials for families and public health and health care professionals relevant to the screening and treatment of CCHD.

(6) CONSULTATION.—In carrying out programs under this subsection, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with other Federal agencies; State and local agencies, including those responsible for newborn screening and early

intervention services under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), under the Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) (State Children's Health Insurance Program), under the Maternal and Child Health Block Grant Program under title V of the Social Security Act (42 U.S.C. 701 et seq.), and under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 et seq.); consumer groups of, and those that serve, individuals with congenital heart defect and families of such individuals; appropriate national medical and other health and education specialty organizations; persons living with critical congenital heart defect and families of such persons; other qualified professional personnel who are proficient in congenital heart defect, CCHD, and related conditions, and who possess the specialized knowledge, skills, and attributes needed to serve newborns, infants, toddlers, and children diagnosed with congenital heart defect and families of such newborns, infants, toddlers, and children; third-party payers and managed care organizations; and related commercial industries.

(7) POLICY DEVELOPMENT.—The Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall coordinate and collaborate to develop and update recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical, and other health and education professional-based organizations, with respect to newborn screening, evaluation, diagnosis, and intervention programs and systems. Such recommendations and updates shall be made available on the public Web site of the Department of Health and Human Services.

(c) DEFINITIONS.—For purposes of this section:

(1) The term ''CCHD'' means critical congenital heart defect.

(2) The term ''newborn CCHD screening'' means objective physiologic procedures to detect possible congenital heart problems and to identify newborns and infants who require further medical evaluations or interventions.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be nec-

essary to carry out this section for each of fiscal years 2017 through 2021.

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