(D) treatment approaches; and

(E) outcome measures, such that analysis of the outcome measures will allow derivation of evidence-based best practices and guidelines for congenital heart disease patients; and

(3) may ensure the collection and analysis of longitudinal data related to individuals of all ages with congenital heart disease, including infants, young children, adolescents, and adults of all ages.

(d) Public access

The Congenital Heart Disease Surveillance System shall be made available to the public, as appropriate, including congenital heart disease researchers.

(e) Patient privacy

The Secretary shall ensure that the Congenital Heart Disease Surveillance System is maintained in a manner that complies with the regulations promulgated under section 264 of the Health Insurance Portability and Accountability Act of 1996.

(f) Eligibility for grant

To be eligible to receive a grant under subsection (a)(2), an entity shall—

(1) be a public or private nonprofit entity with specialized experience in congenital heart disease; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(July 1, 1944, ch. 373, title III, § 399V–2, as added Pub. L. 111–148, title X, § 10411(b)(1), Mar. 23, 2010, 124 Stat. 988.)

REFERENCES IN TEXT

Section 264 of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (e), is section 264 of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

§ 280g–14. National diabetes prevention program

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a national diabetes prevention program (referred to in this section as the ''program'') targeted at adults at high risk for diabetes in order to eliminate the preventable burden of diabetes.

(b) Program activities

The program described in subsection (a) shall include—

(1) a grant program for community-based diabetes prevention program model sites;

(2) a program within the Centers for Disease Control and Prevention to determine eligibility of entities to deliver community-based diabetes prevention services;

(3) a training and outreach program for lifestyle intervention instructors; and

(4) evaluation, monitoring and technical assistance, and applied research carried out by the Centers for Disease Control and Prevention.

(c) Eligible entities

To be eligible for a grant under subsection (b)(1), an entity shall be a State or local health department, a tribal organization, a national network of community-based non-profits focused on health and wellbeing, an academic institution, or other entity, as the Secretary determines.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, § 399V–3, as added Pub. L. 111–148, title X, § 10501(g), Mar. 23, 2010, 124 Stat. 996.)

§ 280g–15. State demonstration programs to evaluate alternatives to current medical tort litigation

(a) In general

The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations. In awarding such grants, the Secretary shall ensure the diversity of the alternatives so funded.

(b) Duration

The Secretary may award grants under subsection (a) for a period not to exceed 5 years.

(c) Conditions for demonstration grants

(1) Requirements

Each State desiring a grant under subsection (a) shall develop an alternative to current tort litigation that—

(A) allows for the resolution of disputes over injuries allegedly caused by health care providers or health care organizations; and

(B) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care.

(2) Alternative to current tort litigation

Each State desiring a grant under subsection (a) shall demonstrate how the proposed alternative described in paragraph (1)(A)—

(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes;

(B) encourages the efficient resolution of disputes;

(C) encourages the disclosure of health care errors;

(D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events;

(E) improves access to liability insurance;

(F) fully informs patients about the differences in the alternative and current tort litigation;

(G) provides patients the ability to opt out of or voluntarily withdraw from participat-

ing in the alternative at any time and to pursue other options, including litigation, outside the alternative;

(H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and

(I) would not limit or curtail a patient's existing legal rights, ability to file a claim in or access a State's legal system, or otherwise abrogate a patient's ability to file a medical malpractice claim.

(3) Sources of compensation

Each State desiring a grant under subsection (a) shall identify the sources from and methods by which compensation would be paid for claims resolved under the proposed alternative to current tort litigation, which may include public or private funding sources, or a combination of such sources. Funding methods shall to the extent practicable provide financial incentives for activities that improve patient safety.

(4) Scope

(A) In general

Each State desiring a grant under subsection (a) shall establish a scope of jurisdiction (such as Statewide, designated geographic region, a designated area of health care practice, or a designated group of health care providers or health care organizations) for the proposed alternative to current tort litigation that is sufficient to evaluate the effects of the alternative. No scope of jurisdiction shall be established under this paragraph that is based on a health care payer or patient population.

(B) Notification of patients

A State shall demonstrate how patients would be notified that they are receiving health care services that fall within such scope, and the process by which they may opt out of or voluntarily withdraw from participating in the alternative. The decision of the patient whether to participate or continue participating in the alternative process shall be made at any time and shall not be limited in any way.

(5) Preference in awarding demonstration grants

In awarding grants under subsection (a), the Secretary shall give preference to States—

(A) that have developed the proposed alternative through substantive consultation with relevant stakeholders, including patient advocates, health care providers and health care organizations, attorneys with expertise in representing patients and health care providers, medical malpractice insurers, and patient safety experts;

(B) that make proposals that are likely to enhance patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; and

(C) that make proposals that are likely to improve access to liability insurance.

(d) Application

(1) In general

Each State desiring a grant under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(2) Review panel

(A) In general

In reviewing applications under paragraph (1), the Secretary shall consult with a review panel composed of relevant experts appointed by the Comptroller General.

(B) Composition

(i) Nominations

The Comptroller General shall solicit nominations from the public for individuals to serve on the review panel.

(ii) Appointment

The Comptroller General shall appoint, at least 9 but not more than 13, highly qualified and knowledgeable individuals to serve on the review panel and shall ensure that the following entities receive fair representation on such panel:

(I) Patient advocates.

(II) Health care providers and health care organizations.

(III) Attorneys with expertise in representing patients and health care providers.

(IV) Medical malpractice insurers.

(V) State officials.

(VI) Patient safety experts.

(C) Chairperson

The Comptroller General, or an individual within the Government Accountability Office designated by the Comptroller General, shall be the chairperson of the review panel.

(D) Availability of information

The Comptroller General shall make available to the review panel such information, personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

(E) Information from agencies

The review panel may request directly from any department or agency of the United States any information that such panel considers necessary to carry out its duties. To the extent consistent with applicable laws and regulations, the head of such department or agency shall furnish the requested information to the review panel.

(e) Reports

(1) By State

Each State receiving a grant under subsection (a) shall submit to the Secretary an annual report evaluating the effectiveness of activities funded with grants awarded under such subsection. Such report shall, at a minimum, include the impact of the activities funded on patient safety and on the availability and price of medical liability insurance.

(2) By Secretary

The Secretary shall submit to Congress an annual compendium of the reports submitted

under paragraph (1) and an analysis of the activities funded under subsection (a) that examines any differences that result from such activities in terms of the quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance.

(f) Technical assistance

(1) In general

The Secretary shall provide technical assistance to the States applying for or awarded grants under subsection (a).

(2) Requirements

Technical assistance under paragraph (1) shall include—

(A) guidance on non-economic damages, including the consideration of individual facts and circumstances in determining appropriate payment, guidance on identifying avoidable injuries, and guidance on disclosure to patients of health care errors and adverse events; and

(B) the development, in consultation with States, of common definitions, formats, and data collection infrastructure for States receiving grants under this section to use in reporting to facilitate aggregation and analysis of data both within and between States.

(3) Use of common definitions, formats, and data collection infrastructure

States not receiving grants under this section may also use the common definitions, formats, and data collection infrastructure developed under paragraph (2)(B).

(g) Evaluation

(1) In general

The Secretary, in consultation with the review panel established under subsection (d)(2), shall enter into a contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of grants awarded under subsection (a) and to annually prepare and submit a report to Congress. Such an evaluation shall begin not later than 18 months following the date of implementation of the first program funded by a grant under subsection (a).

(2) Contents

The evaluation under paragraph (1) shall include—

(A) an analysis of the effects of the grants awarded under subsection (a) with regard to the measures described in paragraph (3);

(B) for each State, an analysis of the extent to which the alternative developed under subsection (c)(1) is effective in meeting the elements described in subsection (c)(2);

(C) a comparison among the States receiving grants under subsection (a) of the effectiveness of the various alternatives developed by such States under subsection (c)(1);

(D) a comparison, considering the measures described in paragraph (3), of States receiving grants approved under subsection (a) and similar States not receiving such grants; and

(E) a comparison, with regard to the measures described in paragraph (3), of—

(i) States receiving grants under subsection (a);

(ii) States that enacted, prior to March 23, 2010, any cap on non-economic damages; and

(iii) States that have enacted, prior to March 23, 2010, a requirement that the complainant obtain an opinion regarding the merit of the claim, although the substance of such opinion may have no bearing on whether the complainant may proceed with a case.

(3) Measures

The evaluations under paragraph (2) shall analyze and make comparisons on the basis of—

(A) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations;

(B) the nature and number of claims in which tort litigation was pursued despite the existence of an alternative under subsection (a);

(C) the disposition of disputes and claims, including the length of time and estimated costs to all parties;

(D) the medical liability environment;

(E) health care quality;

(F) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events;

(G) patient and health care provider and organization satisfaction with the alternative under subsection (a) and with the medical liability environment; and

(H) impact on utilization of medical services, appropriately adjusted for risk.

(4) Funding

The Secretary shall reserve 5 percent of the amount appropriated in each fiscal year under subsection (k) to carry out this subsection.

(h) MedPAC and MACPAC reports

(1) MedPAC

The Medicare Payment Advisory Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], and its beneficiaries.

(2) MACPAC

The Medicaid and CHIP Payment and Access Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicaid or CHIP programs under titles XIX and XXI of the Social Security Act [42 U.S.C. 1396 et seq., 1397aa et seq.], and their beneficiaries.

(3) Reports

Not later than December 31, 2016, the Medicare Payment Advisory Commission and the

Medicaid and CHIP Payment and Access Commission shall each submit to Congress a report that includes the findings and recommendations of each respective Commission based on independent reviews conducted under paragraphs (1) and (2), including an analysis of the impact of the alternatives reviewed on the efficiency and effectiveness of the respective programs.

(i) Option to provide for initial planning grants

Of the funds appropriated pursuant to subsection (k), the Secretary may use a portion not to exceed $500,000 per State to provide planning grants to such States for the development of demonstration project applications meeting the criteria described in subsection (c). In selecting States to receive such planning grants, the Secretary shall give preference to those States in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation.

(j) Definitions

In this section:

(1) Health care services

The term ''health care services'' means any services provided by a health care provider, or by any individual working under the supervision of a health care provider, that relate to—

(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

(B) the assessment of the health of human beings.

(2) Health care organization

The term ''health care organization'' means any individual or entity which is obligated to provide, pay for, or administer health benefits under any health plan.

(3) Health care provider

The term ''health care provider'' means any individual or entity—

(A) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

(B) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

(k) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $50,000,000 for the 5-fiscal year period beginning with fiscal year 2011.

***(l)* Current State efforts to establish alternative to tort litigation**

Nothing in this section shall be construed to limit any prior, current, or future efforts of any State to establish any alternative to tort litigation.

(m) Rule of construction

Nothing in this section shall be construed as limiting states'[1] authority over or responsibility for their state[1] justice systems.

(July 1, 1944, ch. 373, title III, § 399V–4, as added Pub. L. 111–148, title X, § 10607, Mar. 23, 2010, 124 Stat. 1009.)

[1] So in original. Probably should be capitalized.

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (h)(1), (2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§ 1395 et seq.), XIX (§ 1396 et seq.), and XXI (§ 1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§ 280g–16. Food Safety Integrated Centers of Excellence

(a) In general

Not later than 1 year after January 4, 2011, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2), shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this section as the ''Centers of Excellence'') to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. The Centers of Excellence shall be headquartered at selected State health departments.

(b) Selection of Centers of Excellence

(1) Eligible entities

To be eligible to be designated as a Center of Excellence under subsection (a), an entity shall—

(A) be a State health department;

(B) partner with 1 or more institutions of higher education that have demonstrated knowledge, expertise, and meaningful experience with regional or national food production, processing, and distribution, as well as leadership in the laboratory, epidemiological, and environmental detection and investigation of foodborne illness; and

(C) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.

(2) Working group

Not later than 180 days after January 4, 2011, the Secretary shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence.

(3) Additional Centers of Excellence

The Secretary may designate eligible entities to be regional Food Safety Centers of Excellence, in addition to the 5 Centers designated under subsection (a).

(c) Activities

Under the leadership of the Director of the Centers for Disease Control and Prevention, each Center of Excellence shall be based out of a selected State health department, which shall provide assistance to other regional, State, and local departments of health through activities that include—

(1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;