

Subsec. (b)(1). Pub. L. 115-328, §3(2)(B)(i), substituted “programs, including those to test and evaluate strategies, which, in collaboration with States, localities, tribes, and community organizations, support the provision of” for “programs to test and evaluate various strategies to provide” in introductory provisions.

Subsec. (b)(1)(B). Pub. L. 115-328, §3(2)(B)(iii), added subpar. (B). Former subpar. (B) redesignated (C).

Subsec. (b)(1)(C). Pub. L. 115-328, §3(2)(B)(ii), (iv), redesignated subpar. (B) as (C) and inserted “, and the risks of non-medically indicated deliveries before full term” before semicolon at end. Former subpar. (C) redesignated (D).

Subsec. (b)(1)(D). Pub. L. 115-328, §3(2)(B)(ii), redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Subsec. (b)(1)(D)(ii). Pub. L. 115-328, §3(2)(B)(v)(I), inserted “intake” after “folic acid”.

Subsec. (b)(1)(D)(iv) to (vii). Pub. L. 115-328, §3(2)(B)(v)(II)-(IV), added cls. (iv) to (vi) and redesignated former cl. (iv) as (vii).

Subsec. (b)(1)(E) to (G). Pub. L. 115-328, §3(2)(B)(ii), (vi)-(viii), redesignated subpars. (D) to (F) as (E) to (G), respectively, and struck out subpar. (G), as redesignated, which read as follows: “utilization of evidence-based strategies to prevent birth injuries;”.

Subsec. (b)(2). Pub. L. 115-328, §3(2)(C), inserted “, as well as prevention of a future preterm birth” before semicolon at end.

2013—Subsec. (b)(1). Pub. L. 113-55, §103(b)(1)(A), added subpars. (A) to (F) and struck out former subpars. (A) to (F) which read as follows:

“(A) the signs of preterm labor, updated as new research results become available;

“(B) the screening for and the treating of infections;

“(c) counseling on optimal weight and good nutrition, including folic acid;

“(D) smoking cessation education and counseling;

“(E) stress management; and

“(F) appropriate prenatal care;”.

Subsec. (b)(2). Pub. L. 113-55, §103(b)(1)(B), added par. (2) and struck out former par. (2) which read as follows: “programs to improve the treatment and outcomes for babies born premature, including the use of evidence-based standards of care by health care professionals for pregnant women at risk of preterm labor or other serious complications and for infants born preterm and at a low birthweight;”.

Subsec. (c). Pub. L. 113-55, §103(b)(2), substituted “\$1,900,000 for each of fiscal years 2014 through 2018.” for “\$5,000,000 for each of fiscal years 2007 through 2011.”

§ 280g-6. Chronic kidney disease initiatives

(a) In general

The Secretary shall establish pilot projects to—

(1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) regarding chronic kidney disease, focusing on prevention;

(2) increase screening for chronic kidney disease, focusing on Medicare beneficiaries at risk of chronic kidney disease; and

(3) enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease.

(b) Scope and duration

(1) Scope

The Secretary shall select at least 3 States in which to conduct pilot projects under this section.

(2) Duration

The pilot projects under this section shall be conducted for a period that is not longer than 5 years and shall begin on January 1, 2009.

(c) Evaluation and report

The Comptroller General of the United States shall conduct an evaluation of the pilot projects conducted under this section. Not later than 12 months after the date on which the pilot projects are completed, the Comptroller General shall submit to Congress a report on the evaluation.

(d) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for the purpose of carrying out this section.

(July 1, 1944, ch. 373, title III, §399R, as added Pub. L. 110-275, title I, §152(a), July 15, 2008, 122 Stat. 2551.)

Editorial Notes

CODIFICATION

Another section 399R of act July 1, 1944, ch. 373, as added by Pub. L. 110-373, §2, Oct. 8, 2008, 122 Stat. 4047, was renumbered section 399S and is classified to section 280g-7 of this title.

Another section 399R of act July 1, 1944, ch. 373, as added by Pub. L. 110-374, §3, Oct. 8, 2008, 122 Stat. 4051, was renumbered section 399T and is classified to section 280g-8 of this title.

Executive Documents

EX. ORD. NO. 13879. ADVANCING AMERICAN KIDNEY HEALTH

Ex. Ord. No. 13879, July 10, 2019, 84 F.R. 33817, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose.* My Administration is dedicated to advancing American kidney health. The state of care for patients with chronic kidney disease and end-stage renal disease (ESRD) is unacceptable: too many at-risk patients progress to late-stage kidney failure; the mortality rate is too high; current treatment options are expensive and do not produce an acceptable quality of life; and there are not enough kidneys donated to meet the current demand for transplants.

Kidney disease was the ninth-leading cause of death in the United States in 2017. Approximately 37 million Americans have chronic kidney disease and more than 726,000 have ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year; fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant.

SEC. 2. *Policy.* It is the policy of the United States to:

(a) prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;

(b) increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and

(c) increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.

SEC. 3. *Announcing an Awareness Initiative on Kidney and Related Diseases.* Within 120 days of the date of this order [July 10, 2019], the Secretary of Health and Human Services (Secretary) shall launch an awareness initiative at the Department of Health and Human Services (Department) to aid the Secretary’s efforts to educate patients and support programs that promote kidney disease awareness. The initiative shall develop

proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease; to improve kidney transplantation; and to share information with patients and providers to enhance awareness of the causes and consequences of kidney disease.

SEC. 4. *Payment Model to Identify and Treat At-Risk Populations Earlier in Disease Development.* Within 30 days of the date of this order, the Secretary shall select a payment model to test innovations in compensation for providers of kidney care services based on kidney patient cost and quality outcomes. The model should broaden the range of care and Medicare payment options available to potential participants with a focus on delaying or preventing the onset of kidney failure, preventing unnecessary hospitalizations, and increasing the rate of transplants. It should aim at achieving these outcomes by creating incentives to provide care for Medicare beneficiaries who have advanced stages of kidney disease but who are not yet on dialysis. The selected model shall include options for flexible advance payments for nephrologists to better support their management and coordination of care for patients with kidney disease.

SEC. 5. *Payment Model to Increase Home Dialysis and Kidney Transplants.* Within 30 days of the date of this order, the Secretary shall select a payment model to evaluate the effects of creating payment incentives for greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis. The model should adjust payments based on the percentage of a participating provider's attributed patients who either are on home dialysis or have received a kidney transplant and should include a learning system to help participants improve performance. Greater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis and may eliminate the need for dialysis altogether for many patients.

SEC. 6. *Encouraging the Development of an Artificial Kidney.* Within 120 days of the date of this order, in order to increase breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available, the Secretary shall:

(a) announce that the Department will consider requests for premarket approval of wearable or implantable artificial kidneys in order to encourage their development and to enhance cooperation between developers and the Food and Drug Administration; and

(b) produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between the Department and the American Society of Nephrology.

SEC. 7. *Increasing Utilization of Available Organs.* (a) Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance.

(b) Within 180 days of the date of this order, the Secretary shall streamline and expedite the process of kidney matching and delivery to reduce the discard rate. Removing process inefficiencies in matching and delivery that result in delayed acceptance by transplant centers will reduce the detrimental effects on organ quality of prolonged time with reduced or cut-off blood supply.

SEC. 8. *Supporting Living Organ Donors.* Within 90 days of the date of this order, the Secretary shall propose a regulation to remove financial barriers to living organ donation. The regulation should expand the definition of allowable costs that can be reimbursed under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation program, raise the limit on the income of donors eligible for reimbursement under the program, allow reimbursement for lost-wage expenses, and provide for reimbursement of child-care and elder-care expenses.

SEC. 9. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

§ 280g-7. Amyotrophic lateral sclerosis registry

(a) Establishment

(1) In general

Not later than 1 year after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, if scientifically advisable—

(A) develop a system to collect data on amyotrophic lateral sclerosis (referred to in this section as “ALS”) and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

(B) establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(2) Purpose

It is the purpose of the registry established under paragraph (1)(B) to—

(A) better describe the incidence and prevalence of ALS in the United States;

(B) examine appropriate factors, such as environmental and occupational, that may be associated with the disease;

(C) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease;

(D) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

(E) other matters as recommended by the Advisory Committee established under subsection (b).

(b) Advisory Committee

(1) Establishment

Not later than 180 days after October 8, 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the “Advisory Committee”). The Advisory Committee shall be composed of not more