Cosmetic Act (21 U.S.C. 301 et seq.) for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

"(2) RULE OF CONSTRUCTION.—Nothing in this subsection should be construed to establish or contribute to a medical standard of care."

§290dd-4. Program to support coordination and continuation of care for drug overdose patients

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall identify or facilitate the development of best practices for—

(1) emergency treatment of known or suspected drug overdose;

(2) the use of recovery coaches, as appropriate, to encourage individuals who experience a non-fatal overdose to seek treatment for substance use disorder and to support coordination and continuation of care;

(3) coordination and continuation of care and treatment, including, as appropriate, through referrals, of individuals after a drug overdose; and

(4) the provision or prescribing of overdose reversal medication, as appropriate.

(b) Grant establishment and participation

(1) In general

The Secretary shall award grants on a competitive basis to eligible entities to support implementation of voluntary programs for care and treatment of individuals after a drug overdose, as appropriate, which may include implementation of the best practices described in subsection (a).

(2) Eligible entity

In this section, the term ''eligible entity'' means—

(A) a State substance abuse agency;

(B) an Indian Tribe or tribal organization; or

(C) an entity that offers treatment or other services for individuals in response to, or following, drug overdoses or a drug overdose, such as an emergency department, in consultation with a State substance abuse agency.

(3) Application

An eligible entity desiring a grant under this section shall submit an application to the Secretary, at such time and in such manner as the Secretary may require, that includes—

(A) evidence that such eligible entity carries out, or is capable of contracting and coordinating with other community entities to carry out, the activities described in paragraph (4):

(B) evidence that such eligible entity will work with a recovery community organization to recruit, train, hire, mentor, and supervise recovery coaches and fulfill the requirements described in paragraph (4)(A); and

(C) such additional information as the Secretary may require.

(4) Use of grant funds

An eligible entity awarded a grant under this section shall use such grant funds to(A) hire or utilize recovery coaches to help support recovery, including by—

(i) connecting patients to a continuum of care services, such as—

(I) treatment and recovery support programs;

(II) programs that provide non-clinical recovery support services;

(III) peer support networks;

(IV) recovery community organizations;

(V) health care providers, including physicians and other providers of behavioral health and primary care;

(VI) education and training providers;

(VII) employers;

(VIII) housing services; and

(IX) child welfare agencies;

(ii) providing education on overdose prevention and overdose reversal to patients and families, as appropriate;

(iii) providing follow-up services for patients after an overdose to ensure continued recovery and connection to support services;

(iv) collecting and evaluating outcome data for patients receiving recovery coaching services; and

(v) providing other services the Secretary determines necessary to help ensure continued connection with recovery support services, including culturally appropriate services, as applicable;

(B) establish policies and procedures, pursuant to Federal and State law, that address the provision of overdose reversal medication, the administration of all drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and all biological products licensed under section 262 of this title to treat substance use disorder, and subsequent continuation of, or referral to, evidence-based treatment for patients with a substance use disorder who have experienced a non-fatal drug overdose, in order to support long-term treatment, prevent relapse, and reduce recidivism and future overdose; and

(C) establish integrated models of care for individuals who have experienced a non-fatal drug overdose which may include patient assessment, follow up, and transportation to and from treatment facilities.

(5) Additional permissible uses

In addition to the uses described in paragraph (4), a grant awarded under this section may be used, directly or through contractual arrangements, to provide—

(A) all drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and all biological products licensed under section 262 of this title to treat substance use disorders or reverse overdose, pursuant to Federal and State law;

(B) withdrawal and detoxification services that include patient evaluation, stabilization, and preparation for treatment of substance use disorder, including treatment described in subparagraph (A), as appropriate; or

(C) mental health services provided by a certified professional who is licensed and qualified by education, training, or experience to assess the psychosocial background of patients, to contribute to the appropriate treatment plan for patients with substance use disorder, and to monitor patient progress.

(6) Preference

In awarding grants under this section, the Secretary shall give preference to eligible entities that meet any or all of the following criteria:

(A) The eligible entity is a critical access hospital (as defined in section 1395x(mm)(1)of this title), a low volume hospital (as defined in section 1395ww(d)(12)(C)(i) of such title), a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of such title), or a hospital that receives disproportionate share hospital payments under section 1395ww(d)(5)(F) of this title.

(B) The eligible entity is located in a State with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention, or under the jurisdiction of an Indian Tribe with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined through appropriate mechanisms as determined by the Secretary in consultation with Indian Tribes.

(C) The eligible entity demonstrates that recovery coaches will be placed in both health care settings and community settings.

(7) Period of grant

A grant awarded to an eligible entity under this section shall be for a period of not more than 5 years.

(c) Definitions

In this section:

(1) Indian Tribe; tribal organization

The terms "Indian Tribe" and "tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 5304 of title 25.

(2) Recovery coach

the 1 term ''recovery coach'' means an individual—

(A) with knowledge of, or experience with, recovery from a substance use disorder; and

(B) who has completed training from, and is determined to be in good standing by, a recovery services organization capable of conducting such training and making such determination.

(3) Recovery community organization

The term "recovery community organization" has the meaning given such term in section 290ee-2(a) of this title.

(d) Reporting Requirements

(1) Reports by grantees

Each eligible entity awarded a grant under this section shall submit to the Secretary an annual report for each year for which the entity has received such grant that includes information on—

(A) the number of individuals treated by the entity for non-fatal overdoses, including the number of non-fatal overdoses where overdose reversal medication was administered:

(B) the number of individuals administered medication-assisted treatment by the entity;

(C) the number of individuals referred by the entity to other treatment facilities after a non-fatal overdose, the types of such other facilities, and the number of such individuals admitted to such other facilities pursuant to such referrals; and

(D) the frequency and number of patients with reoccurrences, including readmissions for non-fatal overdoses and evidence of relapse related to substance use disorder.

(2) Report by Secretary

Not later than 5 years after October 24, 2018, the Secretary shall submit to Congress a report that includes an evaluation of the effectiveness of the grant program carried out under this section with respect to long term health outcomes of the population of individuals who have experienced a drug overdose, the percentage of patients treated or referred to treatment by grantees, and the frequency and number of patients who experienced relapse, were readmitted for treatment, or experienced another overdose.

(e) Privacy

The requirements of this section, including with respect to data reporting and program oversight, shall be subject to all applicable Federal and State privacy laws.

(f) Authorization of appropriations

There is authorized to be appropriated to carry out this section \$10,000,000 for each of fiscal years 2019 through 2023.

(Pub. L. 115-271, title VII, §7081, Oct. 24, 2018, 132 Stat. 4032.)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(4)(B), (5)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (\S 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

¹So in original. Probably should be capitalized.

§ 290ee. Opioid overdose reversal medication access and education grant programs

(a) Grants to States

The Secretary shall make grants to States to—

(1) implement strategies for pharmacists to dispense a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected opioid overdose, as appropriate, pursuant to a standing order:

(2) encourage pharmacies to dispense opioid overdose reversal medication pursuant to a standing order;

(3) develop or provide training materials that persons authorized to prescribe or dispense a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose may use to educate the public concerning—

(A) when and how to safely administer such drug or device; and

(B) steps to be taken after administering such drug or device; and

(4) educate the public concerning the availability of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose without a person-specific prescription.

(b) Certain requirement

A grant may be made under this section only if the State involved has authorized standing orders to be issued for drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(c) Preference in making grants

In making grants under this section, the Secretary may give preference to States that have a significantly higher rate of opioid overdoses than the national average, and that—

(1) have not implemented standing orders regarding drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;

(2) authorize standing orders to be issued that permit community-based organizations, substance abuse programs, or other nonprofit entities to acquire, dispense, or administer drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; or

(3) authorize standing orders to be issued that permit police, fire, or emergency medical services agencies to acquire and administer drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(d) Grant terms

(1) Number

A State may not receive more than one grant under this section at a time.

(2) Period

A grant under this section shall be for a period of 3 years.

(3) Limitation

A State may use not more than 20 percent of a grant under this section for educating the public pursuant to subsection (a)(4).

(e) Applications

To be eligible to receive a grant under this section, a State shall submit an application to the Secretary in such form and manner and containing such information as the Secretary may reasonably require, including detailed proposed expenditures of grant funds.

(f) Reporting

A State that receives a grant under this section shall, at least annually for the duration of the grant, submit a report to the Secretary evaluating the progress of the activities supported through the grant. Such reports shall include information on the number of pharmacies in the State that dispense a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose under a standing order, and other information as the Secretary determines appropriate to evaluate the use of grant funds.

(g) Definitions

In this section the term "standing order" means a document prepared by a person authorized to prescribe medication that permits another person to acquire, dispense, or administer medication without a person-specific prescription.

(h) Authorization of appropriations

(1) In general

To carry out this section, there are authorized to be appropriated \$5,000,000 for the period of fiscal years 2017 through 2019.

(2) Administrative costs

Not more than 3 percent of the amounts made available to carry out this section may be used by the Secretary for administrative expenses of carrying out this section.

(July 1, 1944, ch. 373, title V, §545, as added Pub. L. 114–198, title I, §110(a), July 22, 2016, 130 Stat. 709.)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

PRIOR PROVISIONS

A prior section 290ee, act July 1, 1944, ch. 373, title V, §545, formerly Pub. L. 92–255, title V, §502, as added Pub. L. 94–237, §12(b)(1), Mar. 19, 1976, 90 Stat. 247, and amended Pub. L. 95–461, §5, Oct. 14, 1978, 92 Stat. 1269; Pub. L. 96–181, §11, Jan. 2, 1980, 93 Stat. 1315; renumbered §524 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(15), 97 Stat. 181; renumbered §545, Stat. 181; Stat. 1