

any of the following activities, but may use not more than 20 percent of the grant funds for activities described in paragraphs (3) and (4):

(1) To establish a program for prescribing 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.

(2) To train and provide resources for health care providers and pharmacists on the prescribing of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(3) To purchase drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, for distribution under the program described in paragraph (1).

(4) To offset the co-payments and other cost sharing associated with drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(5) To establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication-assisted treatment and appropriate counseling and behavioral therapies.

(d) Evaluations by recipients

As a condition of receipt of a grant under this section, an eligible entity shall, for each year for which the grant is received, submit to the Secretary an evaluation of activities funded by the grant which contains such information as the Secretary may reasonably require.

(e) Reports by the Secretary

Not later than 5 years after the date on which the first grant under this section is awarded, the Secretary shall submit to the appropriate committees of the House of Representatives and of the Senate a report aggregating the information received from the grant recipients for such year under subsection (d) and evaluating the outcomes achieved by the programs funded by grants awarded under this section.

(f) Authorization of appropriations

There is authorized to be appropriated to carry out this section, \$5,000,000 for the period of fiscal years 2017 through 2021.

(July 1, 1944, ch. 373, title V, §544, as added Pub. L. 114-198, title I, §107(a), July 22, 2016, 130 Stat. 703.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(1) and (c)(1) to (4), 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 290dd-3, act July 1, 1944, ch. 373, title V, §544, formerly Pub. L. 91-616, title III, §333, Dec. 31, 1970, 84 Stat. 1853, as amended Pub. L. 93-282, title I, §122(a), May 14, 1974, 88 Stat. 131; Pub. L. 94-581, title I, §111(c)(4), Oct. 21, 1976, 90 Stat. 2852; renumbered §523 of act July 1, 1944, Apr. 26, 1983, Pub. L. 98-24, §2(b)(13), 97

Stat. 181; Aug. 27, 1986, Pub. L. 99-401, title I, §106(a), 100 Stat. 907; renumbered §544, July 22, 1987, Pub. L. 100-77, title VI, §611(2), 101 Stat. 516; June 13, 1991, Pub. L. 102-54, §13(q)(1)(A)(ii), 105 Stat. 278, which related to confidentiality of patient records for alcohol abuse and alcoholism programs, was omitted in the general revision of this part by Pub. L. 102-321. See section 290dd-2 of this title.

IMPROVING ACCESS TO OVERDOSE TREATMENT

Pub. L. 114-198, title I, §107(b), July 22, 2016, 130 Stat. 705, provided that:

“(1) INFORMATION ON BEST PRACTICES.—Not later than 180 days after the date of enactment of this Act [July 22, 2016]:

“(A) The Secretary of Health and Human Services may provide information to prescribers within Federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))), and the health care facilities of the Indian Health Service, on best practices for prescribing or co-prescribing 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, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

“(B) The Secretary of Defense may provide information to prescribers within Department of Defense medical facilities on best practices for prescribing or co-prescribing 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, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

“(C) The Secretary of Veterans Affairs may provide information to prescribers within Department of Veterans Affairs medical facilities on best practices for prescribing or co-prescribing 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, 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.”

§ 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.)

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, July 22, 1987, Pub. L. 100-77, title VI, §611(2), 101 Stat. 516; Nov. 4, 1988, Pub. L. 100-607, title VIII, §813(3), 102 Stat. 3170; Nov. 7, 1988, Pub. L. 100-628, title VI, §613(3), 102 Stat. 3243; Aug. 16, 1989, Pub. L. 101-93, §5(t)(1), 103 Stat. 615, which related to technical assistance to State and local agencies by the National Institute on Drug Abuse, was omitted in the general revision of this part by Pub. L. 102-321.

§ 290ee-1. First responder training

(a) Program authorized

The Secretary shall make grants to States, local governmental entities, and Indian tribes and tribal organizations (as defined in section 5304 of title 25) to allow first responders and members of other key community sectors to administer 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.

(b) Application

(1) In general

An entity seeking a grant under this section shall submit an application to the Secretary—

(A) that meets the criteria under paragraph (2); and

(B) at such time, in such manner, and accompanied by such information as the Secretary may require.

(2) Criteria

An entity, in submitting an application under paragraph (1), shall—