

115TH CONGRESS  
2D SESSION

# S. 2700

To provide emergency assistance to States, territories, Tribal nations, and local areas affected by the opioid epidemic and to make financial assistance available to States, territories, Tribal nations, local areas, and public or private nonprofit entities to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals with substance use disorder and their families.

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## IN THE SENATE OF THE UNITED STATES

APRIL 18, 2018

Ms. WARREN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To provide emergency assistance to States, territories, Tribal nations, and local areas affected by the opioid epidemic and to make financial assistance available to States, territories, Tribal nations, local areas, and public or private nonprofit entities to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals with substance use disorder and their families.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the  
 3 “Comprehensive Addiction Resources Emergency Act of  
 4 2018”.

5 (b) TABLE OF CONTENTS.—The table of contents of  
 6 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Purpose.

Sec. 3. Amendment to the Public Health Service Act.

“TITLE XXXIV—SUBSTANCE USE AND OPIOID HEALTH  
 RESOURCES

“Subtitle A—Substance Use and Opioid Emergency Relief Grant Program

“Sec. 3401. Establishment of program of grants.

“Sec. 3402. Planning council.

“Sec. 3403. Amount of grant and use of amounts.

“Sec. 3404. Application.

“Sec. 3405. Technical assistance.

“Sec. 3406. Authorization of appropriations.

“Subtitle B—State and Tribal Substance Use Disorder Prevention and  
 Intervention Grant Program

“Sec. 3411. Establishment of program of grants.

“Sec. 3412. Amount of grant and use of amounts.

“Sec. 3413. Application and limitation.

“Sec. 3414. Technical assistance.

“Sec. 3415. Authorization of appropriations.

“Subtitle C—Other Grant Program

“Sec. 3421. Establishment of grant program.

“Sec. 3422. Use of amounts.

“Sec. 3423. Technical assistance.

“Sec. 3424. Planning and development grants.

“Sec. 3425. Authorization of appropriations.

“Subtitle D—Miscellaneous Provisions

“Sec. 3431. Special projects of national significance.

“Sec. 3432. Education and training centers.

“Sec. 3433. Other provisions.

“Sec. 3434. Standards for substance use disorder treatment and recovery  
 facilities.

“Sec. 3435. Naloxone distribution program.

“Sec. 3436. Additional funding for the National Institutes of Health.

“Sec. 3437. Additional funding for improved data collection and prevention  
 of infectious disease transmission.

“Sec. 3438. Definitions.

Sec. 4. Amendments to the Controlled Substances Act.

1 **SEC. 2. PURPOSE.**

2 It is the purpose of this Act to provide emergency  
 3 assistance to States, territories, Tribal nations, and local  
 4 areas that are disproportionately affected by the opioid  
 5 epidemic and to make financial assistance available to  
 6 States, territories, Tribal nations, local areas, and other  
 7 public or private nonprofit entities to provide for the devel-  
 8 opment, organization, coordination, and operation of more  
 9 effective and cost efficient systems for the delivery of es-  
 10 sential services to individuals and families with substance  
 11 use disorder.

12 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**  
 13 **ACT.**

14 The Public Health Service Act (42 U.S.C. 201 et  
 15 seq.) is amended by adding at the end the following:

16 **“TITLE XXXIV—SUBSTANCE USE**  
 17 **AND OPIOID HEALTH RE-**  
 18 **SOURCES**

19 **“Subtitle A—Substance Use and**  
 20 **Opioid Emergency Relief Grant**  
 21 **Program**

22 **“SEC. 3401. ESTABLISHMENT OF PROGRAM OF GRANTS.**

23 “(a) IN GENERAL.—The Secretary, in coordination  
 24 with the Director of the Office of National Drug Control

1 Policy, shall award grants to eligible localities for the pur-  
 2 pose of addressing substance use within such localities.

3 “(b) ELIGIBILITY.—

4 “(1) IN GENERAL.—To be eligible to receive a  
 5 grant under subsection (a) a locality shall—

6 “(A) be—

7 “(i) a county that can demonstrate  
 8 that the rate of drug overdose deaths per  
 9 100,000 individuals residing in the county  
 10 during the most recent 3-year period for  
 11 which such data are available was not less  
 12 than the rate of such deaths for the county  
 13 that ranked at the 67th percentile of all  
 14 counties, as determined by the Secretary;

15 “(ii) a county that can demonstrate  
 16 that the number of drug overdose deaths  
 17 during the most recent 3-year period for  
 18 which such data are available was not less  
 19 than the number of such deaths for the  
 20 county that ranked at the 90th percentile  
 21 of all counties, as determined by the Sec-  
 22 retary; or

23 “(iii) a city that is located within a  
 24 county described in clause (i) or (ii), that

1                   meets the requirements of paragraph (3);  
2                   and

3                   “(B) submit to the Secretary an applica-  
4                   tion in accordance with section 3404.

5                   “(2) MULTIPLE CONTIGUOUS COUNTIES.—In  
6                   the case of an eligible county that is contiguous to  
7                   one or more other eligible counties within the same  
8                   State, the group of counties shall—

9                   “(A) be considered as a single eligible  
10                  county for purposes of a grant under this sec-  
11                  tion;

12                  “(B) submit a single application under sec-  
13                  tion 3404;

14                  “(C) form a joint planning council (for the  
15                  purposes of section 3402); and

16                  “(D) establish, through intergovernmental  
17                  agreements, an administrative mechanism to al-  
18                  locate funds and substance use disorder treat-  
19                  ment services under the grant based on—

20                         “(i) the number and rate of drug  
21                         overdose deaths and nonfatal drug  
22                         overdoses in each of the counties that com-  
23                         pose the eligible county;

24                         “(ii) the severity of need for services  
25                         in each such county; and

1 “(iii) the health and support per-  
 2 sonnel needs of each such county.

3 “(3) CITIES AND COUNTIES WITHIN MULTIPLE  
 4 CONTIGUOUS COUNTIES.—

5 “(A) IN GENERAL.—A city that is within  
 6 an eligible county described in paragraph (1),  
 7 or a group of counties that is within a group of  
 8 counties determined to be an eligible county  
 9 under paragraph (2), shall be eligible to receive  
 10 a grant under section 3401 if such city or coun-  
 11 ty or group of counties meets the requirements  
 12 of subparagraph (B).

13 “(B) REQUIREMENTS.—A city or county  
 14 meets the requirements of this subparagraph if  
 15 such city or county—

16 “(i) except as provided in subpara-  
 17 graph (C), has a population of not less  
 18 than 50,000 residents;

19 “(ii) meets the requirements of para-  
 20 graph (1)(A);

21 “(iii) submits an application under  
 22 section 3404;

23 “(iv) establishes a planning council  
 24 (for purposes of section 3402); and

1 “(v) establishes an administrative  
2 mechanism to allocate funds and services  
3 under the grant based on—

4 “(I) the number and rate of drug  
5 overdose deaths and nonfatal drug  
6 overdoses in the city or county;

7 “(II) the severity of need for sub-  
8 stance use disorder treatment services  
9 in the city or county; and

10 “(III) the health and support  
11 personnel needs of the city or county.

12 “(C) POPULATION EXCEPTION.—A city or  
13 county or group of counties that does not meet  
14 the requirements of subparagraph (B)(i) may  
15 apply to the Secretary for a waiver of such re-  
16 quirement. Such application shall dem-  
17 onstrate—

18 “(i) that the needs of the population  
19 to be served are distinct or that addressing  
20 substance use in the service area would be  
21 best served by the formation of an inde-  
22 pendent council; and

23 “(ii) that the city or county or group  
24 of counties has the capacity to administer  
25 the funding received under this subtitle.

1           “(D) MINIMUM FUNDING.—A city or coun-  
2           ty that meets the requirement of this paragraph  
3           and receives a grant under section 3401 shall  
4           be entitled to an amount of funding under the  
5           grant in an amount that is not less than the  
6           amount determined under section 3403(a) with  
7           respect to such city or county.

8           “(4) INDEPENDENT CITY.—Independent cities  
9           that are not located within the territory of a county  
10          shall be treated as eligible counties for purposes of  
11          this subtitle.

12          “(5) POLITICAL SUBDIVISIONS.—With respect  
13          to States that do not have a local county system of  
14          governance, the Secretary shall determine the local  
15          political subdivisions within such States that are eli-  
16          gible to receive a grant under section 3401 and such  
17          subdivisions shall be treated as eligible counties for  
18          purposes of this subtitle.

19          “(6) DETERMINATIONS WHERE THERE IS A  
20          LACK OF DATA.—The Secretary shall establish eligi-  
21          bility and allocation criteria related to the prevalence  
22          of drug overdose deaths, the mortality rate from  
23          drug overdoses, and that provides an equivalent  
24          measure of need for funding for cities and counties

1 for which the data described in paragraph (1)(A) or  
 2 (2)(D)(i) is not available.

3 “(7) STUDY.—Not later than 3 years after the  
 4 date of enactment of this title, the Comptroller Gen-  
 5 eral shall conduct a study to determine whether the  
 6 data utilized for purposes of paragraph (1)(A) pro-  
 7 vides the most precise measure of local area need re-  
 8 lated to substance use and addiction prevalence and  
 9 whether additional data would provide more precise  
 10 measures of substance use and addiction prevalence  
 11 in local areas. Such study shall identify barriers to  
 12 collecting or analyzing such data, and make rec-  
 13 ommendations for revising the indicators used under  
 14 such paragraph to determine eligibility in order to  
 15 direct funds to the local areas in most need of fund-  
 16 ing to provide assistance related to substance use  
 17 and addiction.

18 “(8) REFERENCE.—For purposes of this sub-  
 19 title, the term ‘eligible local area’ includes—

20 “(A) a city or county described in para-  
 21 graph (1);

22 “(B) multiple contiguous counties de-  
 23 scribed in paragraph (2);

24 “(C) an independent locality described in  
 25 paragraph (3);

1           “(D) an independent city described in  
2 paragraph (4); and

3           “(E) a political subdivision described in  
4 paragraph (5).

5       “(c) ADMINISTRATION.—

6           “(1) IN GENERAL.—Assistance made available  
7 under a grant awarded under this section shall be  
8 directed to the chief elected official of the eligible  
9 local area who shall administer the grant funds.

10       “(2) MULTIPLE CONTIGUOUS COUNTIES.—

11           “(A) IN GENERAL.—Except as provided in  
12 subparagraph (B), in the case of an eligible  
13 county described in subsection (b)(2), assist-  
14 ance made available under a grant awarded  
15 under this section shall be directed to the chief  
16 elected official of the particular county des-  
17 ignated in the application submitted for the  
18 grant under section 3404. Such chief elected of-  
19 ficial shall be the administrator of the grant.

20           “(B) STATE ADMINISTRATION.—Notwith-  
21 standing subparagraph (A), the eligible county  
22 described in subsection (b)(2) may elect to des-  
23 ignate the chief elected State official of the  
24 State in which the eligible county is located as  
25 the administrator of the grant funds.

1 **“SEC. 3402. PLANNING COUNCIL.**

2       “(a) ESTABLISHMENT.—To be eligible to receive a  
3 grant under section 3401, the chief elected official of the  
4 eligible local area shall establish or designate a substance  
5 use disorder treatment and services planning council that  
6 shall, to the maximum extent practicable—

7               “(1) be representative of the demographics of  
8 the population of individuals with substance use dis-  
9 order in the area; and

10              “(2) include representatives of—

11                      “(A) health care providers, including feder-  
12 ally qualified health centers, rural health clinics,  
13 Indian health programs as defined in section 4  
14 of the Indian Health Care Improvement Act,  
15 urban Indian organizations as defined in section  
16 4 of the Indian Health Care Improvement Act,  
17 Native Hawaiian organizations as defined in  
18 section 12 of the Native Hawaiian Health Care  
19 Act of 1988, and facilities operated by the De-  
20 partment of Veterans Affairs;

21                      “(B) community-based health, harm reduc-  
22 tion, or addiction service organizations, includ-  
23 ing, where applicable, representatives of Drug  
24 Free Communities Coalition grantees;

1           “(C) social service providers, including pro-  
2           viders of housing and homelessness services and  
3           recovery residence providers;

4           “(D) mental health care providers;

5           “(E) local public health agencies;

6           “(F) law enforcement officials, including  
7           officials from High Intensity Drug Trafficking  
8           Area program, where applicable;

9           “(G) affected communities, including indi-  
10          viduals with substance use disorder or a history  
11          of substance use disorder, including individuals  
12          in recovery from substance use disorders;

13          “(H) State governments, including the  
14          State Medicaid agency and the Single State  
15          Agency for Substance Abuse Services;

16          “(I) local governments;

17          “(J) non-elected community leaders;

18          “(K) substance use disorder treatment pro-  
19          viders;

20          “(L) Indian tribes and tribal organizations  
21          as defined in section 4 of the Indian Self-Deter-  
22          mination and Education Assistance Act;

23          “(M) urban Indians as defined in section 4  
24          of the Indian Health Care Improvement Act;

1           “(N) historically underserved groups and  
2           subpopulations;

3           “(O) individuals who were formerly incar-  
4           cerated;

5           “(P) organizations serving individuals who  
6           are currently or were formerly incarcerated;

7           “(Q) representatives of Federal agencies;

8           “(R) representatives of organizations that  
9           provide services to youth at risk of substance  
10          use;

11          “(S) representatives of medical examiners  
12          or coroners;

13          “(T) representatives of labor unions and  
14          the workplace community; and

15          “(U) representatives of local fire depart-  
16          ments and emergency medical services.

17          “(b) METHOD OF PROVIDING FOR COUNCIL.—

18               “(1) IN GENERAL.—In providing for a council  
19               for purposes of subsection (a), the chief elected offi-  
20               cial of the eligible local area may establish the coun-  
21               cil directly or designate an existing entity to serve as  
22               the council, subject to paragraph (2).

23               “(2) CONSIDERATION REGARDING DESIGNATION  
24               OF COUNCIL.—In making a determination of wheth-  
25               er to establish or designate a council under para-

1 graph (1), the chief elected official shall give priority  
2 to the designation of an existing entity that has  
3 demonstrated experience in the provision of health  
4 and support services to individuals with substance  
5 use disorder within the eligible local area, that has  
6 a structure that recognizes the Federal trust respon-  
7 sibility when spending Federal health care dollars,  
8 and that has demonstrated a commitment to re-  
9 specting the obligation of government agencies using  
10 Federal dollars to consult with Indian tribes and  
11 confer with Urban Indian health programs.

12 “(3) JOINT COUNCIL.—The Secretary shall es-  
13 tablish a process to permit an eligible local area that  
14 is not contiguous with any other eligible local area  
15 to form a joint planning council with such other eli-  
16 gible local area or areas, as long as such areas are  
17 located in geographical proximity to each other, as  
18 determined by the Secretary, and submit a joint ap-  
19 plication under section 3404.

20 “(4) JOINT COUNCIL ACROSS STATE LINES.—  
21 Eligible local areas may form a joint planning coun-  
22 cil with other eligible local areas across State lines  
23 if such areas are located in geographical proximity  
24 to each other, as determined by the Secretary, sub-  
25 mit a joint application under section 3404, and es-

1       tablish intergovernmental agreements to allow the  
2       administration of the grant across State lines.

3       “(c) MEMBERSHIP.—Members of the planning coun-  
4       cil established or designated under subsection (a) shall—

5               “(1) be nominated and selected through an  
6       open process;

7               “(2) elect from among their membership a chair  
8       and vice chair;

9               “(3) include at least one representative from  
10       Indian tribes located within any eligible local area  
11       that receives funding under the grant program es-  
12       tablished in section 3401; and

13               “(4) serve no more than 3 consecutive years on  
14       the planning council.

15       “(d) MEMBERSHIP TERMS.—Members of the plan-  
16       ning council established or designated under subsection  
17       (a) may serve additional terms if nominated and selected  
18       through the process established in subsection (c)(1).

19       “(e) DUTIES.—The planning council established or  
20       designated under subsection (a) shall—

21               “(1) establish priorities for the allocation of  
22       grant funds within the eligible local area that em-  
23       phasize reducing drug overdose and substance use  
24       disorder through evidence-based interventions in

1 both community and criminal justice settings and  
2 that are based on—

3 “(A) the use by the grantee of substance  
4 use disorder treatment and intervention strate-  
5 gies that comply with best practices identified  
6 by the Secretary;

7 “(B) the demonstrated or probable cost-ef-  
8 fectiveness of proposed substance use disorder  
9 treatment services;

10 “(C) the health priorities of the commu-  
11 nities within the eligible local area that are af-  
12 fected by substance use;

13 “(D) the priorities and needs of individuals  
14 with substance use disorder; and

15 “(E) the availability of other governmental  
16 and nongovernmental services;

17 “(2) ensure the use of grant funds are con-  
18 sistent with any existing State or local plan regard-  
19 ing the provision of substance use disorder treat-  
20 ment services to individuals with substance use dis-  
21 order;

22 “(3) in the absence of a State or local plan,  
23 work with local public health agencies to develop a  
24 comprehensive plan for the organization and delivery  
25 of substance use disorder treatment services;

1           “(4) regularly assess the efficiency of the ad-  
2           ministrative mechanism in rapidly allocating funds  
3           to support evidence-based substance use disorder  
4           treatment services in the areas of greatest need  
5           within the eligible local area;

6           “(5) work with local public health agencies to  
7           determine the size and demographics of the popu-  
8           lation of individuals with substance use disorders  
9           and the types of substance use that are most preva-  
10          lent in the eligible local area;

11          “(6) work with local public health agencies to  
12          determine the needs of such population, including  
13          the need for substance use disorder treatment serv-  
14          ices;

15          “(7) work with local public agencies to deter-  
16          mine the disparities in access to services among af-  
17          fected subpopulations and historically underserved  
18          communities, including infrastructure and capacity  
19          shortcomings of providers that contribute to these  
20          disparities;

21          “(8) work with local public agencies to establish  
22          methods for obtaining input on community needs  
23          and priorities, including by partnering with organi-  
24          zations that serve targeted communities experiencing  
25          high opioid related health disparities to gather data

1 using culturally attuned data collection methodolo-  
 2 gies;

3 “(9) coordinate with Federal grantees that pro-  
 4 vide substance use disorder treatment services within  
 5 the eligible local area; and

6 “(10) annually assess the effectiveness of the  
 7 substance use disorder treatment services being sup-  
 8 ported by the grant received by the eligible local  
 9 area, including—

10 “(A) reductions in the rates of overdose  
 11 and death from substance use disorders;

12 “(B) rates of discontinuation from sub-  
 13 stance use disorder treatment services;

14 “(C) long-term outcomes among individ-  
 15 uals receiving treatment for substance use dis-  
 16 orders; and

17 “(D) the availability of substance use dis-  
 18 order treatment services needed by individuals  
 19 with substance use disorders over their life-  
 20 times.

21 “(f) CONFLICTS OF INTEREST.—

22 “(1) IN GENERAL.—The planning council under  
 23 subsection (a) may not be directly involved in the  
 24 administration of a grant under section 3401.

1           “(2) REQUIRED AGREEMENTS.—An individual  
2           may serve on the planning council under subsection  
3           (a) only if the individual agrees that if the individual  
4           has a financial interest in an entity, if the individual  
5           is an employee of a public or private entity, or if the  
6           individual is a member of a public or private organi-  
7           zation, and such entity or organization is seeking  
8           amounts from a grant under section 3401, the indi-  
9           vidual will not, with respect to the purpose for which  
10          the entity seeks such amounts, participate (directly  
11          or in an advisory capacity) in the process of select-  
12          ing entities to receive such amounts for such pur-  
13          pose.

14          “(g) GRIEVANCE PROCEDURES.—A planning council  
15          under subsection (a) shall develop procedures for address-  
16          ing grievances with respect to funding under this subtitle,  
17          including procedures for submitting grievances that can-  
18          not be resolved to binding arbitration. Such procedures  
19          shall be described in the by-laws of the planning council.

20          “(h) PUBLIC DELIBERATIONS.—With respect to a  
21          planning council under subsection (a), in accordance with  
22          criteria established by the Secretary, the following applies:

23                  “(1) The meetings of the council shall be open  
24                  to the public and shall be held only after adequate  
25                  notice to the public.

1           “(2) The records, reports, transcripts, minutes,  
2           agenda, or other documents which were made avail-  
3           able to or prepared for or by the council shall be  
4           available for public inspection and copying at a sin-  
5           gle location.

6           “(3) Detailed minutes of each meeting of the  
7           council shall be kept. The accuracy of all minutes  
8           shall be certified to by the chair of the council.

9           “(4) This subparagraph does not apply to any  
10          disclosure of information of a personal nature that  
11          would constitute a clearly unwarranted invasion of  
12          personal privacy, including any disclosure of medical  
13          information or personnel matters.

14   **“SEC. 3403. AMOUNT OF GRANT AND USE OF AMOUNTS.**

15          “(a) AMOUNT OF GRANT.—

16               “(1) GRANTS BASED ON RELATIVE NEED OF  
17          AREA.—

18                   “(A) IN GENERAL.—In carrying out this  
19                  subtitle, the Secretary shall make a grant for  
20                  each eligible local area for which an application  
21                  under section 3404 has been approved. Each  
22                  such grant shall be made in an amount deter-  
23                  mined in accordance with paragraph (3).

24                   “(B) EXPEDITED DISTRIBUTION.—Not  
25                  later than 90 days after an appropriation be-

comes available to carry out this subtitle for a fiscal year, the Secretary shall disburse 53 percent of the amount made available under section 3406 for carrying out this subtitle for such fiscal year through grants to eligible local areas under section 3401, in accordance with subparagraphs (C) and (D).

“(C) AMOUNT.—

“(i) IN GENERAL.—Subject to the extent of amounts made available in appropriations Acts, a grant made for purposes of this subparagraph to an eligible local area shall be made in an amount equal to the product of—

“(I) an amount equal to the amount available for distribution under subparagraph (B) for the fiscal year involved; and

“(II) the percentage constituted by the ratio of the distribution factor for the eligible local area to the sum of the respective distribution factors for all eligible local areas;

which product shall then, as applicable, be increased under subparagraph (D).

“(ii) DISTRIBUTION FACTOR.—For purposes of clause (i)(II), the term ‘distribution factor’ means—

“(I) an amount equal to—

“(aa) the estimated number of drug overdose deaths in the eligible local area, as determined under clause (iii); or

“(bb) the estimated number of non-fatal drug overdoses in the eligible local area, as determined under clause (iv);

as determined by the Secretary based on which distribution factor (item (aa) or (bb)) will result in the eligible local area receiving the greatest amount of funds; or

“(II) in the case of an eligible local area for which the data described in subclause (I) is not available, an amount determined by the Secretary—

“(aa) based on other data the Secretary determines appropriate; and

1                   “(bb) that is related to the  
2                   prevalence of non-fatal drug  
3                   overdoses, drug overdose deaths,  
4                   and the mortality rate from drug  
5                   overdoses and provides an equiv-  
6                   alent measure of need for fund-  
7                   ing.

8                   “(iii) NUMBER OF DRUG OVERDOSE  
9                   DEATHS.—The number of drug overdose  
10                  deaths determined under this clause for an  
11                  eligible county for a fiscal year for pur-  
12                  poses of clause (ii) is the number of drug  
13                  overdose deaths during the most recent 3-  
14                  year period for which such data are avail-  
15                  able.

16                  “(iv) NUMBER OF NON-FATAL DRUG  
17                  OVERDOSES.—The number of non-fatal  
18                  drug overdose deaths determined under  
19                  this clause for an eligible county for a fis-  
20                  cal year for purposes of clause (ii) may be  
21                  determined by using data including emer-  
22                  gency department syndromic data, visits,  
23                  or other emergency medical services for  
24                  drug-related causes during the most recent

1 3-year period for which such data are  
2 available.

3 “(v) STUDY.—Not later than 3 years  
4 after the date of enactment of this title,  
5 the Comptroller General shall conduct a  
6 study to determine whether the data uti-  
7 lized for purposes of clause (ii) provide the  
8 most precise measure of local area need re-  
9 lated to substance use and addiction preva-  
10 lence in local areas and whether additional  
11 data would provide more precise measures  
12 of substance use and addiction prevalence  
13 in local areas. Such study shall identify  
14 barriers to collecting or analyzing such  
15 data, and make recommendations for revis-  
16 ing the distribution factors used under  
17 such clause to determine funding levels in  
18 order to direct funds to the local areas in  
19 most need of funding to provide substance  
20 use disorder treatment services.

21 “(vi) REDUCTIONS IN AMOUNTS.—If a  
22 local area that is an eligible local area for  
23 a year loses such eligibility in a subsequent  
24 year based on the failure to meet the re-

quirements of section 3401(b)(1)(A), such  
area will remain eligible to receive—

“(I) for such subsequent year, an  
amount equal to 80 percent of the  
amount received under the grant in  
the previous year; and

“(II) for the second such subse-  
quent year, an amount equal to 50  
percent of the amount received in the  
such previous year.

“(2) SUPPLEMENTAL GRANTS.—

“(A) IN GENERAL.—The Secretary shall  
disburse the remainder of amounts not dis-  
bursed under paragraph (1) for such fiscal year  
for the purpose of making grants to cities and  
counties whose application under section  
3404—

“(i) contains a report concerning the  
dissemination of emergency relief funds  
under paragraph (1) and the plan for utili-  
zation of such funds, if applicable;

“(ii) demonstrates the need in such  
local area, on an objective and quantified  
basis, for supplemental financial assistance  
to combat substance use disorder;

1           “(iii) demonstrates the existing com-  
2           mitment of local resources of the area,  
3           both financial and in-kind, to combating  
4           substance use disorder;

5           “(iv) demonstrates the ability of the  
6           area to utilize such supplemental financial  
7           resources in a manner that is immediately  
8           responsive and cost effective;

9           “(v) demonstrates that resources will  
10          be allocated in accordance with the local  
11          demographic incidence of substance use  
12          disorders and drug overdose mortality;

13          “(vi) demonstrates the inclusiveness of  
14          affected communities and individuals with  
15          substance use disorders, including those  
16          communities and individuals that are dis-  
17          proportionately affected or historically un-  
18          derserved;

19          “(vii) demonstrates the manner in  
20          which the proposed services are consistent  
21          with the local needs assessment and the  
22          statewide coordinated statement of need  
23          required in section 3413(e);

1 “(viii) demonstrates success in identi-  
2 fying individuals with substance use dis-  
3 orders; and

4 “(ix) demonstrates that support for  
5 substance use disorder treatment services  
6 is organized to maximize the value to the  
7 population to be served with an appro-  
8 priate mix of substance use disorder treat-  
9 ment services and attention to transition in  
10 care.

11 “(B) AMOUNT.—

12 “(i) IN GENERAL.—The amount of  
13 each grant made for purposes of this para-  
14 graph shall be determined by the Sec-  
15 retary. In making such determination, the  
16 Secretary shall consider—

17 “(I) the rate of drug overdose  
18 deaths per 100,000 population in the  
19 eligible local area; and

20 “(II) the increasing need for sub-  
21 stance use disorder treatment serv-  
22 ices, including relative rates of in-  
23 crease in the number of drug  
24 overdoses or drug overdose deaths, re-  
25 cent increases in drug overdoses or

1 drug overdose deaths since data was  
2 provided under section 3401(b), if ap-  
3 plicable.

4 “(ii) DEMONSTRATED NEED.—The  
5 factors considered by the Secretary in de-  
6 termining whether a local area has a dem-  
7 onstrated need for purposes of clause  
8 (i)(II) may include any or all of the fol-  
9 lowing:

10 “(I) The unmet need for sub-  
11 stance use disorder treatment serv-  
12 ices, including factors identified in  
13 subparagraph (B)(i)(II).

14 “(II) Relative rates of increase in  
15 the number of drug overdoses or drug  
16 overdose deaths.

17 “(III) The relative rates of in-  
18 crease in the number of drug  
19 overdoses or drug overdose deaths  
20 within new or emerging subpopula-  
21 tions.

22 “(IV) The current prevalence of  
23 substance use disorders.

24 “(V) Relevant factors related to  
25 the cost and complexity of delivering

1 substance use disorder treatment serv-  
2 ices to individuals in the eligible local  
3 area.

4 “(VI) The impact of co-morbid  
5 factors, including co-occurring condi-  
6 tions, determined relevant by the Sec-  
7 retary.

8 “(VII) The prevalence of home-  
9 lessness among individuals with sub-  
10 stance use disorders.

11 “(VIII) The relevant factors that  
12 limit access to health care, including  
13 geographic variation, adequacy of  
14 health insurance coverage, and lan-  
15 guage barriers.

16 “(IX) The impact of a decline in  
17 the amount received pursuant to para-  
18 graph (1) on substance use disorder  
19 treatment services available to all in-  
20 dividuals with substance use disorders  
21 identified and eligible under this sub-  
22 title.

23 “(X) The increasing incidence in  
24 conditions related to substance use,  
25 including hepatitis C, human immuno-

1                   deficiency virus, hepatitis B and other  
 2                   infections associated with injection  
 3                   drug use.

4                   “(C) APPLICATION OF PROVISIONS.—A  
 5                   local area that receives a grant under this para-  
 6                   graph—

7                   “(i) shall use amounts received in ac-  
 8                   cordance with subsection (b);

9                   “(ii) shall not have to meet the eligi-  
 10                  ble criteria in section 3401(b); and

11                  “(iii) shall not have to establish a  
 12                  planning council under section 3402.

13                  “(3) AMOUNT OF GRANT TO TRIBAL GOVERN-  
 14                  MENTS.—

15                  “(A) INDIAN TRIBES.—In this section, the  
 16                  term ‘Indian tribe’ has the meaning given such  
 17                  term in section 4 of the Indian Self-Determina-  
 18                  tion and Education Assistance Act.

19                  “(B) FORMULA GRANTS.—The Secretary,  
 20                  acting through the Indian Health Service, shall  
 21                  use 10 percent of the amount available under  
 22                  section 3406 for each fiscal year to provide for-  
 23                  mula grants to Indian tribes disproportionately  
 24                  affected by substance use, in an amount deter-  
 25                  mined pursuant to a formula and eligibility cri-

1           teria developed by the Secretary in consultation  
2           with Indian tribes, for the purposes of address-  
3           ing substance use.

4           “(C) USE OF AMOUNTS.—Notwithstanding  
5           any requirements in this section, an Indian  
6           tribe may use amounts provided under grants  
7           awarded under this paragraph for the uses  
8           identified in subsection (b) and any other activi-  
9           ties determined appropriate by the Secretary, in  
10          consultation with Indian tribes.

11       “(b) USE OF AMOUNTS.—

12           “(1) REQUIREMENTS.—The Secretary may not  
13          make a grant under section 3401 to an eligible local  
14          area unless the chief elected official of the area  
15          agrees that—

16           “(A) the allocation of funds and services  
17          within the area under the grant will be made in  
18          accordance with the priorities established by the  
19          substance use disorder treatment services plan-  
20          ning council; and

21           “(B) funds provided under this grant will  
22          be expended for—

23           “(i) prevention services described in  
24          paragraph (3);

1 “(ii) core medical services described in  
2 paragraph (4);

3 “(iii) recovery and support services  
4 described in paragraph (5);

5 “(iv) early intervention and engage-  
6 ment services described in paragraph (6);

7 “(v) harm reduction services described  
8 in paragraph (7);

9 “(vi) financial assistance with health  
10 insurance described in paragraph (8); and

11 “(vii) administrative expenses de-  
12 scribed in paragraph (10).

13 “(2) DIRECT FINANCIAL ASSISTANCE.—

14 “(A) IN GENERAL.—An eligible local area  
15 shall use amounts received under a grant under  
16 section 3401 to provide direct financial assist-  
17 ance to eligible entities for the purpose of pro-  
18 viding prevention services, core medical services,  
19 recovery and support services, harm reduction  
20 services, and early intervention and engagement  
21 services.

22 “(B) APPROPRIATE ENTITIES.—Direct fi-  
23 nancial assistance may be provided under sub-  
24 paragraph (A) to public or nonprofit private en-  
25 tities, or private for-profit entities if such enti-

1           ties are the only available provider of quality  
 2           substance use disorder treatment services in the  
 3           area.

4           “(3) PREVENTION SERVICES.—

5                 “(A) IN GENERAL.—For purposes of this  
 6           subsection, the term ‘prevention services’ means  
 7           services, programs, or multi-sector strategies to  
 8           prevent substance use disorder (such as evi-  
 9           dence-based education campaigns, community-  
 10          based prevention programs, opioid diversion,  
 11          collection and disposal or unused opioids, and  
 12          services to at-risk populations).

13                “(B) LIMIT.—An eligible local area may  
 14          use not to exceed 20 percent of the amount of  
 15          the grant under section 3401 for prevention  
 16          services. An eligible local area may apply to the  
 17          Secretary for a waiver of this subparagraph.

18                “(4) CORE MEDICAL SERVICES.—For purposes  
 19          of this subsection, the term ‘core medical services’  
 20          means the following evidence-based services provided  
 21          to individuals with substance use disorder or at risk  
 22          for developing substance use disorder:

23                 “(A) Substance use disorder treatments,  
 24           including clinical stabilization services, with-  
 25           drawal management and detoxification, inten-

sive inpatient treatment, intensive outpatient treatment, all forms of Federally-approved medication-assisted treatment, outpatient treatment, and residential recovery treatment.

“(B) Outpatient and ambulatory health services, including those administered by Federally qualified health centers and rural health clinics.

“(C) Hospice services.

“(D) Mental health services.

“(E) Naloxone procurement, distribution, and training.

“(F) Pharmaceutical assistance and diagnostic testing related to the management of substance-use disorders a co-morbid conditions.

“(G) Home and community based health services.

“(H) Comprehensive Case Management, including substance use disorder treatment adherence services.

“(I) Health insurance enrollment and cost-sharing assistance in accordance with paragraph (8).

“(5) RECOVERY AND SUPPORT SERVICES.—For purposes of paragraph (1)(B)(ii), the term ‘recovery

1 and support services’ means services, subject to the  
2 approval of the Secretary, that are provided to indi-  
3 viduals with substance use disorder, including resi-  
4 dential recovery treatment and housing, including  
5 for individuals receiving medication-assisted treat-  
6 ment, long term recovery services, 24/7 hotline crisis  
7 center support, medical transportation services, res-  
8 pite care for persons caring for individuals with sub-  
9 stance use disorder, child care and family services  
10 while an individual is receiving inpatient treatment  
11 services or at the time of outpatient services, out-  
12 reach services, peer recovery services, nutrition serv-  
13 ices, and referrals for job training and career serv-  
14 ices, housing, legal services, and child care and fam-  
15 ily services.

16 “(6) EARLY INTERVENTION AND ENGAGEMENT  
17 SERVICES.—For purposes of this section, the term  
18 ‘early intervention and engagement services’ means  
19 services to provide rapid access to substance use dis-  
20 order treatment, counseling provided to individuals  
21 who have misused substances, who have experienced  
22 an overdose, or are at risk of developing substance  
23 use disorder, and the provision of referrals to facili-  
24 tate the access of such individuals to core medical  
25 services or recovery and support services. The enti-

ties through which such services may be provided include emergency rooms, fire departments and emergency medical services, detention facilities, homeless shelters, law enforcement agencies, health care points of entry specified by eligible local areas, Federally qualified health centers, and rural health clinics.

“(7) HARM REDUCTION SERVICES.—For purposes of this section, the term ‘harm reduction services’ means evidence-based services provided to individuals engaging in substance use that reduce the risk of infectious disease transmission, overdose, or death, including by increasing access to health care.

“(8) AFFORDABLE HEALTH INSURANCE COVERAGE.—An eligible local area may use amounts provided under a grant awarded under section 3401 to establish a program of financial assistance to assist eligible individuals with substance use disorder in—

“(A) enrolling in health insurance coverage; or

“(B) affording health care services, including assistance paying cost-sharing amounts, including premiums.

1           “(9) REQUIREMENT OF STATUS AS MEDICAID  
2 PROVIDER.—

3           “(A) PROVISION OF SERVICE.—Subject to  
4 paragraph (2), the Secretary may not make a  
5 grant under section 3401 for the provision of  
6 substance use disorder treatment services under  
7 this section in an eligible local area unless, in  
8 the case of any such service that is available  
9 pursuant to the State plan approved under title  
10 XIX of the Social Security Act for the State—

11           “(i) the political subdivision involved  
12 will provide the service directly, and the  
13 political subdivision has entered into a par-  
14 ticipation agreement under the State plan  
15 and is qualified to receive payments under  
16 such plan; or

17           “(ii) the eligible local area involved  
18 will enter into an agreement with a public  
19 or nonprofit private entity under which the  
20 entity will provide the service, and the enti-  
21 ty has entered into such a participation  
22 agreement and is qualified to receive such  
23 payments.

24           “(B) WAIVER.—

“(i) IN GENERAL.—In the case of an entity making an agreement pursuant to subparagraph (A)(ii) regarding the provision of substance use disorder treatment services, the requirement established in such subparagraph shall be waived by the substance use planning council for the area involved if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

“(ii) DETERMINATION.—A determination by the substance use planning council of whether an entity referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the entity accepts voluntary donations for the purpose of providing services to the public.

“(10) ADMINISTRATION AND PLANNING.—An eligible local area shall not use in excess of 10 percent of amounts received under a grant under section 3401 for administration, accounting, reporting,

1 and program oversight functions, including the de-  
 2 velopment of systems to improve data collection and  
 3 data sharing.

4 “(11) INCARCERATED INDIVIDUALS.—Amounts  
 5 received under a grant under section 3401 may be  
 6 used to provide substance use disorder treatment  
 7 services to currently incarcerated individuals.

8 **“SEC. 3404. APPLICATION.**

9 “(a) IN GENERAL.—To be eligible to receive a grant  
 10 under section 3401, an eligible local area shall prepare and  
 11 submit to the Secretary an application in such form, and  
 12 containing such information, as the Secretary shall re-  
 13 quire, including—

14 “(1) a complete accounting of the disbursement  
 15 of any prior grants received under this subtitle by  
 16 the applicant and the results achieved through such  
 17 disbursements;

18 “(2) a demonstration of the extent of local need  
 19 for the funds under the grant and a plan for pro-  
 20 posed substance use disorder treatment services that  
 21 is consistent with local needs, including a com-  
 22 prehensive plan for the use of the grant funds devel-  
 23 oped by the planning council established under sec-  
 24 tion 3402, except that the planning council require-

1       ment shall not apply with respect to areas receiving  
2       supplemental grant funds under section 3403(a)(2);

3           “(3) a demonstration that the area will use  
4       funds in a manner that provides substance use dis-  
5       order treatment services compliant with the evi-  
6       dence-based standards developed in accordance with  
7       section 3434, including all forms of Federally-ap-  
8       proved medication-assisted treatments;

9           “(4) information on the number of individuals  
10      likely to be served by the funds sought, including de-  
11      mographic data on the populations to be served;

12          “(5) key outcomes that will be measured by all  
13      entities that receive assistance, as well as an expla-  
14      nation of how the outcomes will be measured;

15          “(6) a demonstration that resources provided  
16      under the grant will be allocated in accordance with  
17      the local demographic incidence of substance use, in-  
18      cluding allocations for services for children, youths,  
19      and women;

20          “(7) a demonstration that funds received from  
21      a grant under this subtitle in any prior year were ex-  
22      pended in accordance with the priorities established  
23      by the planning council;

24          “(8) a demonstration that at least one rep-  
25      resentative from Indian tribes located within any eli-

1       gible local area are included in the membership of a  
2       planning council;

3               “(9) a demonstration that the confidentiality of  
4       individuals receiving substance use disorder treat-  
5       ment services will be maintained in a manner not in-  
6       consistent with applicable law; and

7               “(10) an explanation of how income, asset, and  
8       medical expense criteria will be established and ap-  
9       plied to those who qualify for assistance under the  
10       program under this subtitle.

11       “(b) ASSURANCES.—To be eligible to receive a grant  
12       under section 3401, the application submitted by the eligi-  
13       ble local area shall include assurances adequate to en-  
14       sure—

15               “(1) that funds received under the grant will be  
16       utilized to supplement not supplant other State or  
17       local funds made available in the year for which the  
18       grant is awarded to provide substance use disorder  
19       treatment services;

20               “(2) that the political subdivisions within the el-  
21       igible local area will maintain the level of expendi-  
22       tures by such political subdivisions for substance  
23       use-related services at a level that is equal to the  
24       level of such expenditures by such political subdivi-  
25       sions for the preceding fiscal year;

1           “(3) that political subdivisions within the eligi-  
2           ble local area will not use funds received under a  
3           grant awarded under section 3401 in maintaining  
4           the level of substance use disorder treatment services  
5           as required in paragraph (2);

6           “(4) that substance use disorder treatment  
7           services provided with assistance made available  
8           under the grant will be provided without regard—

9                   “(A) to the ability of the individual to pay  
10                  for such services; and

11                   “(B) to the current or past health condi-  
12                  tion of the individual to be served;

13           “(5) that substance use disorder treatment  
14           services will be provided in a setting that is acces-  
15           sible to low-income individuals with substance use  
16           disorder, and to individuals with substance use dis-  
17           order residing in rural areas;

18           “(6) that a program of outreach will be pro-  
19           vided to low-income individuals with substance use  
20           disorder to inform such individuals of substance use  
21           disorder treatment services, and to individuals with  
22           substance use disorder residing in rural areas; and

23           “(7) that funds received under a grant awarded  
24           under this subtitle will not be utilized to make pay-  
25           ments for any item or service to the extent that pay-

1       ment has been made, or can reasonably be expected  
 2       to be made, with respect to that item or service  
 3       under any State compensation program, under an  
 4       insurance policy, or under any Federal or State  
 5       health benefits program (except for a program ad-  
 6       ministered by, or providing the services of, the In-  
 7       dian Health Service).

8       “(c) REQUIREMENTS REGARDING IMPOSITION OF  
 9       CHARGES FOR SERVICES.—

10       “(1) IN GENERAL.—The Secretary may not  
 11       make a grant under section 3401 to an eligible local  
 12       area unless the eligible local area provides assur-  
 13       ances that in the provision of substance use disorder  
 14       treatment services with assistance provided under  
 15       the grant—

16       “(A) in the case of individuals with an in-  
 17       come less than or equal to 138 percent of the  
 18       official poverty level, the provider will not im-  
 19       pose charges on any such individual for the  
 20       services provided under the grant;

21       “(B) in the case of individuals with an in-  
 22       come greater than 138 percent of the official  
 23       poverty level, the provider will impose a charge  
 24       on each such individual according to a schedule  
 25       of charges made available to the public;

1           “(C) in the case of individuals with an in-  
2 come greater than 138 percent of the official  
3 poverty level but not exceeding 200 percent of  
4 such poverty level, the provider will not, for an  
5 calendar year, impose charges in an amount ex-  
6 ceeding 5 percent of the annual gross income of  
7 the individual;

8           “(D) in the case of individuals with an in-  
9 come greater than 200 percent of the official  
10 poverty level but not exceeding 300 percent of  
11 such poverty level, the provider will not, for any  
12 calendar year, impose charges in an amount ex-  
13 ceeding 7 percent of the annual gross income of  
14 the individual involved;

15           “(E) in the case of individuals with an in-  
16 come greater than 300 percent of the official  
17 poverty level, the provider will not, for any cal-  
18 endar year, impose charges in an amount ex-  
19 ceeding 15 percent of the annual gross income  
20 of the individual involved; and

21           “(F) in the case of eligible American In-  
22 dian and Alaska Native individuals as defined  
23 by section 447.50 of title 42, Code of Federal  
24 Regulations (as in effect on July 1, 2010), the  
25 provider will not impose any charges for sub-

1           stance use disorder treatment services, includ-  
2           ing any charges or cost-sharing prohibited by  
3           section 1402(d) of the Patient Protection and  
4           Affordable Care Act.

5           “(2) CHARGES.—With respect to compliance  
6           with the assurances made under paragraph (1), an  
7           eligible local area may, in the case of individuals  
8           subject to a charge—

9                   “(A) assess the amount of the charge in  
10                  the discretion of the area, including imposing  
11                  only a nominal charge for the provision of sub-  
12                  stance use disorder treatment services, subject  
13                  to the provisions of the paragraph regarding  
14                  public schedules and regarding limitations on  
15                  the maximum amount of charges; and

16                  “(B) take into consideration the total med-  
17                  ical expenses of individuals in assessing the  
18                  amount of the charge, subject to such provi-  
19                  sions.

20           “(3) AGGREGATE CHARGES.—The Secretary  
21           may not make a grant under section 3401 to an eli-  
22           gible local area unless the area agrees that the limi-  
23           tations on charges for substance use disorder treat-  
24           ment services under this subsection applies to the  
25           annual aggregate of charges imposed for such serv-

1       ices, however the charges are characterized, includes  
2       enrollment fees, premiums, deductibles, cost sharing,  
3       co-payments, co-insurance costs, or any other  
4       charges.

5       “(d) INDIAN TRIBES.—Any application requirements  
6 for grants distributed in accordance with section  
7 3403(a)(3) shall be developed by the Secretary in con-  
8 sultation with Indian tribes.

9       **“SEC. 3405. TECHNICAL ASSISTANCE.**

10       “The Secretary shall, beginning on the date of enact-  
11 ment of this title, provide technical assistance, including  
12 assistance from other grantees, contractors or subcontrac-  
13 tors under this title to assist newly eligible local areas in  
14 the establishment of planning councils and, to assist enti-  
15 ties in complying with the requirements of this subtitle  
16 in order to make such areas eligible to receive a grant  
17 under this subtitle. The Secretary may make planning  
18 grants available to eligible local areas, in an amount not  
19 to exceed \$75,000 for any area, that is projected to be  
20 eligible for funding under section 3401 in the following  
21 fiscal year. Such grant amounts shall be deducted from  
22 the first year formula award to eligible local areas accept-  
23 ing such grants.

1 **“SEC. 3406. AUTHORIZATION OF APPROPRIATIONS.**

2 “There is authorized to be appropriated to carry out  
3 this subtitle—

4 “(1) \$2,700,000,000 for fiscal year 2019;

5 “(2) \$2,700,000,000 for fiscal year 2020;

6 “(3) \$2,700,000,000 for fiscal year 2021;

7 “(4) \$2,700,000,000 for fiscal year 2022;

8 “(5) \$2,700,000,000 for fiscal year 2023;

9 “(6) \$2,700,000,000 for fiscal year 2024;

10 “(7) \$2,700,000,000 for fiscal year 2025;

11 “(8) \$2,700,000,000 for fiscal year 2026;

12 “(9) \$2,700,000,000 for fiscal year 2027; and

13 “(10) \$2,700,000,000 for fiscal year 2028.

14 **“Subtitle B—State and Tribal Sub-**  
15 **stance Use Disorder Prevention**  
16 **and Intervention Grant Pro-**  
17 **gram**

18 **“SEC. 3411. ESTABLISHMENT OF PROGRAM OF GRANTS.**

19 “The Secretary, acting in coordination with the Di-  
20 rector of the Office of National Drug Control Policy, shall  
21 award grants to States, territories, and tribal governments  
22 for the purpose of addressing substance use within such  
23 States.

24 **“SEC. 3412. AMOUNT OF GRANT AND USE OF AMOUNTS.**

25 “(a) AMOUNT OF GRANT TO STATES AND TERRI-  
26 TORIES.—

1 “(1) IN GENERAL.—

2 “(A) EXPEDITED DISTRIBUTION.—Not  
3 later than 90 days after an appropriation be-  
4 comes available, the Secretary shall disburse 50  
5 percent of the amount made available under  
6 section 3415 for carrying out this subtitle for  
7 such fiscal year through grants to States under  
8 section 3411, in accordance with subparagraphs  
9 (B) and (C).

10 “(B) MINIMUM ALLOTMENT.—Subject to  
11 the amount made available under section 3415,  
12 the amount of a grant under section 3411 for—

13 “(i) each of the 50 States, the District  
14 of Columbia, and Puerto Rico for a fiscal  
15 year shall be the greater of—

16 “(I) \$2,000,000; or

17 “(II) an amount determined  
18 under the subparagraph (C); and

19 “(ii) each territory other than Puerto  
20 Rico for a fiscal year shall be the greater  
21 of—

22 “(I) \$500,000; or

23 “(II) an amount determined  
24 under the subparagraph (C).

25 “(C) DETERMINATION.—

1           “(i) FORMULA.—For purposes of sub-  
2 paragraph (B), the amount referred to in  
3 this subparagraph for a State (including a  
4 territory) for a fiscal year is—

5                   “(I) an amount equal to the  
6 amount made available under section  
7 3415 for the fiscal year involved for  
8 grants pursuant to subparagraph (B);  
9 and

10                   “(II) the percentage constituted  
11 by the sum of—

12                           “(aa) the product of 0.85  
13 and the ratio of the State dis-  
14 tribution factor for the State or  
15 territory to the sum of the re-  
16 spective distribution factors for  
17 all States; and

18                           “(bb) the product of 0.15  
19 and the ratio of the non-local dis-  
20 tribution factor for the State or  
21 territory (as determined under  
22 clause (iv)) to the sum of the re-  
23 spective non-local distribution  
24 factors for all States or terri-  
25 tories.

1 “(ii) STATE DISTRIBUTION FACTOR.—

2 For purposes of clause (i)(II)(aa), the term

3 ‘State distribution factor’ means an

4 amount equal to—

5 “(I) the estimated number of

6 drug overdose deaths in the State, as

7 determined under clause (iii); or

8 “(II) the number of non-fatal

9 drug overdoses in the State, as deter-

10 mined under clause (iv);

11 as determined by the Secretary based on

12 which distribution factor (subclause (I) or

13 (II)) will result in the State receiving the

14 greatest amount of funds.

15 “(iii) NUMBER OF DRUG

16 OVERDOSES.—For purposes of clause (ii),

17 the number of drug overdose deaths deter-

18 mined under this clause for a State for a

19 fiscal year is the number of drug overdose

20 deaths during the most recent 3-year pe-

21 riod for which such data are available.

22 “(iv) NUMBER OF NON-FATAL DRUG

23 OVERDOSES.—For purposes of clause (ii),

24 the number of non-fatal drug overdose

25 deaths determined under this clause for

1 State for a fiscal year for purposes of  
 2 clause (ii) may be determined by using  
 3 data including emergency department  
 4 syndromic data, visits, or other emergency  
 5 medical services for drug-related causes  
 6 during the most recent 3-year period for  
 7 which such data are available.

8 “(v) NON-LOCAL DISTRIBUTION FAC-  
 9 TORS.—For purposes of clause (i)(II)(bb),  
 10 the term ‘non-local distribution factor’  
 11 means an amount equal to the sum of—

12 “(I) the number of drug  
 13 overdoses deaths in the State involved,  
 14 as determined under clause (iii), or  
 15 the number of non-fatal drug  
 16 overdoses in the State, based on the  
 17 criteria used by the State under  
 18 clause (ii); less

19 “(II) the total number of drug  
 20 overdose deaths or non-fatal drug  
 21 overdoses that are within areas in  
 22 such State or territory that are eligi-  
 23 ble counties under section 3401.

24 “(vi) STUDY.—Not later than 3 years  
 25 after the date of enactment of this title,

the Comptroller General shall conduct a study to determine whether the data utilized for purposes of clause (ii) provides the most precise measure of State need related to substance use and addiction prevalence and whether additional data would provide more precise measures the levels of substance use and addiction prevalent in States. Such study shall identify barriers to collecting or analyzing such data, and make recommendations for revising the distribution factors used under such clause to determine funding levels in order to direct funds to the States in most need of funding to provide substance use disorder treatment services.

“(2) SUPPLEMENTAL GRANTS.—

“(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall disburse the remainder of amounts not disbursed under paragraph (1) for such fiscal year for the purpose of making grants to States whose application—

“(i) contains a report concerning the dissemination of emergency relief funds

1 under paragraph (1) and the plan for utili-  
2 zation of such funds;

3 “(ii) demonstrates the need in such  
4 State, on an objective and quantified basis,  
5 for supplemental financial assistance to  
6 combat substance use disorder;

7 “(iii) demonstrates the existing com-  
8 mitment of local resources of the State,  
9 both financial and in-kind, to combating  
10 substance use disorder;

11 “(iv) demonstrates the ability of the  
12 State to utilize such supplemental financial  
13 resources in a manner that is immediately  
14 responsive and cost effective;

15 “(v) demonstrates that resources will  
16 be allocated in accordance with the local  
17 demographic incidence of substances use  
18 disorders and drug overdose mortality;

19 “(vi) demonstrates the inclusiveness of  
20 affected communities and individuals with  
21 substance use disorders, including those  
22 communities and individuals that are dis-  
23 proportionately affected or historically un-  
24 derserved;

1 “(vii) demonstrates the manner in  
 2 which the proposed services are consistent  
 3 with the local needs assessment and the  
 4 statewide coordinated statement of need  
 5 required under section 3413(e);

6 “(viii) demonstrates success in identi-  
 7 fying individuals with substance use dis-  
 8 orders; and

9 “(ix) demonstrates that support for  
 10 substance use disorder treatment services  
 11 is organized to maximize the value to the  
 12 population to be served with an appro-  
 13 priate mix of substance use disorder treat-  
 14 ment services and attention to transition in  
 15 care.

16 “(B) AMOUNT.—

17 “(i) IN GENERAL.—The amount of  
 18 each grant made for purposes of this para-  
 19 graph shall be determined by the Sec-  
 20 retary. In making such determination, the  
 21 Secretary shall consider:

22 “(I) the rate of drug overdose  
 23 deaths per 100,000 population in the  
 24 State; and

1 “(II) the increasing need for sub-  
2 stance use disorder treatment serv-  
3 ices, including relative rates of in-  
4 crease in the number of drug  
5 overdoses or drug overdose deaths, or  
6 recent increases in drug overdoses or  
7 drug overdose deaths since the data  
8 was reported under section 3413.

9 “(ii) DEMONSTRATED NEED.—The  
10 factors considered by the Secretary in de-  
11 termining whether a State has a dem-  
12 onstrated need for purposes of subpara-  
13 graph (A)(ii) may include any or all of the  
14 following:

15 “(I) The unmet need for such  
16 services, including the factors identi-  
17 fied in clause (i)(II).

18 “(II) Relative rates of increase in  
19 the number of drug overdoses or drug  
20 overdose deaths.

21 “(III) The relative rates of in-  
22 crease in the number of drug deaths  
23 within new or emerging subpopula-  
24 tions.

1                   “(IV) The current prevalence of  
2 substance use disorders.

3                   “(V) Relevant factors related to  
4 the cost and complexity of delivering  
5 substance use disorder treatment serv-  
6 ices to individuals in the State.

7                   “(VI) The impact of co-morbid  
8 factors, including co-occurring condi-  
9 tions, determined relevant by the Sec-  
10 retary.

11                  “(VII) The prevalence of home-  
12 lessness among individuals with sub-  
13 stance use disorder.

14                  “(VIII) The relevant factors that  
15 limit access to health care, including  
16 geographic variation, adequacy of  
17 health insurance coverage, and lan-  
18 guage barriers.

19                  “(IX) The impact of a decline in  
20 the amount received pursuant to para-  
21 graph (1) on substance use disorder  
22 treatment services available to all in-  
23 dividuals with substance use disorders  
24 identified and eligible under this sub-  
25 title.

1                   “(X) The increasing incidence in  
2                   conditions related to substance use,  
3                   including hepatitis C, human immuno-  
4                   deficiency virus, hepatitis B and other  
5                   infections associated with injection  
6                   drug use.

7                   “(C) MODEL STANDARDS.—

8                   “(i) PREFERENCE.—In determining  
9                   whether a State will receive funds under  
10                  this paragraph, except as provided in  
11                  clause (ii), the Secretary shall give pref-  
12                  erence to States that have adopted the  
13                  model standards developed in accordance  
14                  with section 3434.

15                  “(ii) REQUIREMENT.—Effective begin-  
16                  ning in fiscal year 2025, the Secretary  
17                  shall not award a grant under this para-  
18                  graph to a State unless that State has  
19                  adopted the model standards developed in  
20                  accordance with section 3434.

21                  “(3) AMOUNT OF GRANT TO TRIBAL GOVERN-  
22                  MENTS.—

23                  “(A) INDIAN TRIBES.—In this section, the  
24                  term ‘Indian tribe’ has the meaning given such

1 term in section 4 of the Indian Self-Determina-  
 2 tion and Education Assistance Act.

3 “(B) FORMULA GRANTS.—The Secretary,  
 4 acting through the Indian Health Service, shall  
 5 use 10 percent of the amount available under  
 6 section 3415 for each fiscal year to provide for-  
 7 mula grants to Indian tribes in an amount de-  
 8 termined pursuant to a formula and eligibility  
 9 criteria developed by the Secretary in consulta-  
 10 tion with Indian tribes, for the purposes of ad-  
 11 dressing substance use.

12 “(C) USE OF AMOUNTS.—Notwithstanding  
 13 any requirements in this section, an Indian  
 14 tribe may use amounts provided under grants  
 15 awarded under this paragraph for the uses  
 16 identified in subsection (b) and any other activi-  
 17 ties determined appropriate by the Secretary, in  
 18 consultation with Indian tribes.

19 “(b) USE OF AMOUNTS.—

20 “(1) IN GENERAL.—A State may use amounts  
 21 provided under grants awarded under section 3411  
 22 for—

23 “(A) prevention services described in para-  
 24 graph (2);

1           “(B) core medical services described in  
2 paragraph (3);

3           “(C) recovery and support services de-  
4 scribed in paragraph (4);

5           “(D) early intervention and engagement  
6 services described in paragraph (5);

7           “(E) harm reduction services described in  
8 paragraph (6); and

9           “(F) administrative expenses described in  
10 paragraph (8).

11       “(2) PREVENTION SERVICES.—

12           “(A) IN GENERAL.—For purposes of this  
13 subsection, the term ‘prevention services’ means  
14 services, programs, or multi-sector strategies to  
15 prevent substance use disorder (including evi-  
16 dence-based education campaigns, community-  
17 based prevention programs, opioid diversion,  
18 collection and disposal of unused opioids, and  
19 services to at-risk populations).

20           “(B) LIMIT.—A State may use not to ex-  
21 ceed 20 percent of the amount of the grant  
22 under section 3411 for prevention services. A  
23 State may apply to the Secretary for a waiver  
24 of this subparagraph.

1           “(3) CORE MEDICAL SERVICES.—For purposes  
2           of this subsection, the term ‘core medical services’  
3           means the following evidence-based services when  
4           provided to individuals with substance use disorder  
5           or at risk for developing substance use disorder:

6                   “(A) Substance use disorder treatments,  
7                   including clinical stabilization services, with-  
8                   drawal management and detoxification, inten-  
9                   sive inpatient treatment, intensive outpatient  
10                  treatment, all forms of Federally-approved  
11                  medication-assisted treatment, outpatient treat-  
12                  ment, and residential recovery treatment.

13                  “(B) Outpatient and ambulatory health  
14                  services, including those administered by Feder-  
15                  ally qualified health centers and rural health  
16                  clinics.

17                  “(C) Hospice services.

18                  “(D) Mental health services.

19                  “(E) Naloxone procurement, distribution,  
20                  and training.

21                  “(F) Pharmaceutical assistance related to  
22                  the management of substance-use disorders and  
23                  co-morbid conditions.

24                  “(G) Home and community based health  
25                  services.

1                   “(H) Comprehensive Case Management  
2                   and care coordination, including treatment ad-  
3                   herence services.

4                   “(I) Health insurance enrollment and cost-  
5                   sharing assistance in accordance with sub-  
6                   section (e).

7                   “(4) RECOVERY AND SUPPORT SERVICES.—For  
8                   purposes of paragraph (1)(C), the term ‘recovery  
9                   and support services’ means services, subject to the  
10                  approval of the Secretary, that are provided to indi-  
11                  viduals with substance use disorder, including resi-  
12                  dential recovery treatment and housing, including  
13                  for individuals receiving medication-assisted treat-  
14                  ment, long term recovery services, 24/7 hotline crisis  
15                  center services, medical transportation services, res-  
16                  pite care for persons caring for individuals with sub-  
17                  stance use disorder, child care and family services  
18                  while an individual is receiving inpatient treatment  
19                  services or at the time of outpatient services, out-  
20                  reach services, peer recovery services, nutrition serv-  
21                  ices, and referrals for job training and career serv-  
22                  ices, housing, legal services, and child care and fam-  
23                  ily services.

24                  “(5) EARLY INTERVENTION AND ENGAGEMENT  
25                  SERVICES.—For purposes of this subsection, the

1 term ‘early intervention and engagement services’  
2 means services to provide rapid access to substance  
3 use disorder treatment services, counseling provided  
4 to individuals who have misused substances, who  
5 have experienced an overdose, or are at risk of devel-  
6 oping substance use disorder, and the provision of  
7 referrals to facilitate the access of such individuals  
8 to core medical services or recovery and support  
9 services. The entities through which such services  
10 may be provided include emergency rooms, fire de-  
11 partments and emergency medical services, detention  
12 facilities, homeless shelters, law enforcement agen-  
13 cies, health care points of entry specified by eligible  
14 areas, Federally qualified health centers, and rural  
15 health clinics.

16 “(6) HARM REDUCTION SERVICES.—For pur-  
17 poses of this subsection, the term ‘harm reduction  
18 services’ means evidence-based services provided to  
19 individuals engaging in substance use disorder that  
20 reduce the risk of infectious disease transmission,  
21 overdose, or death, including by increasing access to  
22 health care.

23 “(7) AFFORDABLE HEALTH INSURANCE COV-  
24 ERAGE.—A State may use amounts provided under  
25 a grant awarded under section 3411 to establish a

1 program of financial assistance to assist eligible indi-  
2 viduals with substance use disorder in—

3 “(A) enrolling in health insurance cov-  
4 erage; or

5 “(B) affording health care services, includ-  
6 ing assistance paying cost-sharing amounts, in-  
7 cluding premiums.

8 “(8) ADMINISTRATION AND PLANNING.—A  
9 State shall not use in excess of 10 percent of  
10 amounts received under a grant under section 3411  
11 for administration, accounting, reporting, and pro-  
12 gram oversight functions, including the development  
13 of systems to improve data collection and data shar-  
14 ing.

15 “(9) INCARCERATED INDIVIDUALS.—Amounts  
16 received under a grant under section 3411 may be  
17 used to provide substance use disorder treatment  
18 services to currently incarcerated individuals.

19 **“SEC. 3413. APPLICATION AND LIMITATION.**

20 “(a) APPLICATION.—To be eligible to receive a grant  
21 under section 3411, a State shall prepare and submit to  
22 the Secretary an application in such form, and containing  
23 such information, as the Secretary shall require, includ-  
24 ing—

1           “(1) a complete accounting of the disbursement  
2           of any prior grants received under this subtitle by  
3           the applicant and the results achieved by these ex-  
4           penditures;

5           “(2) a comprehensive plan for the use of the  
6           grant, including a demonstration of the extent of  
7           local need for the funds sought and a plan for pro-  
8           posed substance use disorder treatment services that  
9           is consistent with local needs;

10          “(3) a demonstration that the State will use  
11          funds in a manner that provides substance use dis-  
12          order treatment services compliant with the evi-  
13          dence-based standards developed in accordance with  
14          section 3434, including all Federally-approved medi-  
15          cation-assisted treatments;

16          “(4) information on the number of individuals  
17          likely to be served by the funds sought, including de-  
18          mographic data on the populations to be served;

19          “(5) an identification of key outcomes that will  
20          be measured by all entities that receive assistance,  
21          as well as an explanation of how the outcomes will  
22          be measured;

23          “(6) a demonstration that resources provided  
24          under the grant will be allocated in accordance with  
25          the local demographic incidence of substance use, in-

1 including allocations for services for children, youths,  
2 and women;

3 “(7) a demonstration that funds received from  
4 a grant under this subtitle in any prior year were ex-  
5 pended in accordance with State priorities;

6 “(8) a demonstration that the confidentiality of  
7 individuals receiving substance use disorder treat-  
8 ment services will be maintained in a manner not in-  
9 consistent with applicable law; and

10 “(9) an explanation of how income, asset, and  
11 medical expense criteria will be established and ap-  
12 plied to those who qualify for assistance under the  
13 program.

14 “(b) ASSURANCES.—To be eligible to receive a grant  
15 under section 3401, the application submitted by an eligi-  
16 ble State shall include assurances adequate to ensure—

17 “(1) that funds received under the grant will be  
18 utilized to supplement not supplant other State or  
19 local funds made available in the year for which the  
20 grant is awarded to provide substance use disorder  
21 treatment services to individuals with substance use  
22 disorder;

23 “(2) that the political subdivisions within the  
24 State will maintain the level of expenditures by such  
25 political subdivisions for substance use disorder

1 treatment services at a level that is equal to the level  
2 of such expenditures by such political subdivisions  
3 for the preceding fiscal year;

4 “(3) that political subdivisions within the State  
5 will not use funds received under a grant awarded  
6 under section 3411 in maintaining the level of sub-  
7 stance use disorder treatment services as required in  
8 paragraph (2);

9 “(4) that substance use disorder treatment  
10 services provided with assistance made available  
11 under the grant will be provided without regard—

12 “(A) to the ability of the individual to pay  
13 for such services; and

14 “(B) to the current or past health condi-  
15 tion of the individual to be served;

16 “(5) that substance use disorder treatment  
17 services will be provided in a setting that is acces-  
18 sible to low-income individuals with substance use  
19 disorders and to individuals with substance use dis-  
20 orders residing in rural areas;

21 “(6) that a program of outreach will be pro-  
22 vided to low-income individuals with substance use  
23 disorders to inform such individuals of substance use  
24 disorder treatment services and to individuals with  
25 substance use disorders residing in rural areas;

1           “(7) that Indian tribes are included in planning  
2           for the use of grant funds and that the Federal  
3           trust responsibility is upheld at all levels of program  
4           administration; and

5           “(8) that funds received under a grant awarded  
6           under this section will not be utilized to make pay-  
7           ments for any item or service to the extent that pay-  
8           ment has been made, or can reasonably be expected  
9           to be made, with respect to that item or service  
10          under a State compensation program, under an in-  
11          surance policy, or under any Federal or State health  
12          benefits program (except for a program administered  
13          by or providing the services of the Indian Health  
14          Service).

15          “(c) MEDICAID IMD WAIVER APPLICATION RE-  
16          QUIREMENT.—A State shall not be eligible to receive a  
17          grant under this subtitle for a fiscal year unless the  
18          State—

19                 “(1) has in effect for the year a waiver under  
20                 section 1115 of the Social Security Act (42 U.S.C.  
21                 1315) to provide medical assistance under the State  
22                 plan under title XIX of such Act to individuals  
23                 who—

24                         “(A) have not attained age 65 (or, if the  
25                         State provides the medical assistance described

1 in section 1905(a)(16) of such Act, have at-  
 2 tained age 21 but have not attained age 65);

3 “(B) are patients in an institution for  
 4 mental diseases; and

5 “(C) are eligible for medical assistance  
 6 under the State plan; or

7 “(2) has submitted an application for the year  
 8 for such a waiver.

9 “(d) REQUIREMENTS REGARDING IMPOSITION OF  
 10 CHARGES FOR SERVICES.—

11 “(1) IN GENERAL.—The Secretary may not  
 12 make a grant under section 3411 to a State unless  
 13 the State provides assurances that in the provision  
 14 of services with assistance provided under the  
 15 grant—

16 “(A) in the case of individuals with an in-  
 17 come less than or equal to 138 percent of the  
 18 official poverty level, the provider will not im-  
 19 pose charges on any such individual for the  
 20 services provided under the grant;

21 “(B) in the case of individuals with an in-  
 22 come greater than 138 percent of the official  
 23 poverty level, the provider will impose a charge  
 24 on each such individual according to a schedule  
 25 of charges made available to the public;

1           “(C) in the case of individuals with an in-  
2 come greater than 138 percent of the official  
3 poverty level but not exceeding 200 percent of  
4 such poverty level, the provider will not, for an  
5 calendar year, impose charges in an amount ex-  
6 ceeding 5 percent of the annual gross income of  
7 the individual;

8           “(D) in the case of individuals with an in-  
9 come greater than 200 percent of the official  
10 poverty level but not exceeding 300 percent of  
11 such poverty level, the provider will not, for any  
12 calendar year, impose charges in an amount ex-  
13 ceeding 7 percent of the annual gross income of  
14 the individual involved;

15           “(E) in the case of individuals with an in-  
16 come greater than 300 percent of the official  
17 poverty level, the provider will not, for any cal-  
18 endar year, impose charges in an amount ex-  
19 ceeding 15 percent of the annual gross income  
20 of the individual involved; and

21           “(F) in the case of eligible American In-  
22 dian and Alaska Native individuals as defined  
23 by section 447.50 of title 42, Code of Federal  
24 Regulations (as in effect on July 1, 2010), the  
25 provider will not impose any charges for sub-

1           stance use disorder treatment services, includ-  
2           ing any charges or cost-sharing prohibited by  
3           section 1402(d) of the Patient Protection and  
4           Affordable Care Act.

5           “(2) CHARGES.—With respect to compliance  
6           with the assurances made under paragraph (1), a  
7           State may, in the case of individuals subject to a  
8           charge—

9                   “(A) assess the amount of the charge in  
10                  the discretion of the State, including imposing  
11                  only a nominal charge for the provision of serv-  
12                  ices, subject to the provisions of the paragraph  
13                  regarding public schedules and regarding limi-  
14                  tations on the maximum amount of charges;  
15                  and

16                  “(B) take into consideration the total med-  
17                  ical expenses of individuals in assessing the  
18                  amount of the charge, subject to such provi-  
19                  sions.

20           “(3) AGGREGATE CHARGES.—The Secretary  
21           may not make a grant under section 3411 to a State  
22           unless the State agrees that the limitations on  
23           charges for substance use disorder treatment serv-  
24           ices under this subsection applies to the annual ag-  
25           gregate of charges imposed for such services, how-

1       ever the charges are characterized, includes enroll-  
2       ment fees, premiums, deductibles, cost sharing, co-  
3       payments, co-insurance costs, or any other charges.

4       “(e) STATEWIDE COORDINATED STATEMENT OF  
5 NEED.—A State shall not be eligible to receive a grant  
6 under this subtitle for a fiscal year unless the State devel-  
7 ops and publishes a statewide coordinated statement of  
8 need, including a demonstration of the extent of State  
9 need for assistance in addressing addiction and substance  
10 use disorder in the State and identifying priorities for the  
11 delivery of essential services to individuals with substance  
12 use disorder and their families.

13       “(f) INDIAN TRIBES.—Any application requirements  
14 applying to grants distributed in accordance with section  
15 3412(c) shall be developed by the Secretary in consulta-  
16 tion with Indian tribes.

17 **“SEC. 3414. TECHNICAL ASSISTANCE.**

18       “The Secretary shall provide technical assistance in  
19 administering and coordinating the activities authorized  
20 under section 3412, including technical assistance for the  
21 development of State applications for supplementary  
22 grants authorized in section 3212(a)(2).

23 **“SEC. 3415. AUTHORIZATION OF APPROPRIATIONS.**

24       “There is authorized to be appropriated to carry out  
25 this subtitle—

- 1 “(1) \$4,000,000,000 for fiscal year 2019;
- 2 “(2) \$4,000,000,000 for fiscal year 2020;
- 3 “(3) \$4,000,000,000 for fiscal year 2021;
- 4 “(4) \$4,000,000,000 for fiscal year 2022;
- 5 “(5) \$4,000,000,000 for fiscal year 2023;
- 6 “(6) \$4,000,000,000 for fiscal year 2024;
- 7 “(7) \$4,000,000,000 for fiscal year 2025;
- 8 “(8) \$4,000,000,000 for fiscal year 2026;
- 9 “(9) \$4,000,000,000 for fiscal year 2027; and
- 10 “(10) \$4,000,000,000 for fiscal year 2028.

## 11 **“Subtitle C—Other Grant Program**

### 12 **“SEC. 3421. ESTABLISHMENT OF GRANT PROGRAM.**

13 “(a) IN GENERAL.—The Secretary shall award  
 14 grants to public, nonprofit, and Native entities for the  
 15 purpose of funding core medical services, recovery and  
 16 support services, harm reduction services, administrative  
 17 expenses, and early intervention and engagement services  
 18 in accordance with this section.

19 “(b) ELIGIBILITY.—

20 “(1) ENTITIES.—Public, nonprofit, or Native  
 21 entities eligible to receive a grant under subsection  
 22 (a) may include—

23 “(A) federally qualified health centers  
 24 under section 1905(l)(2)(B) of the Social Secu-  
 25 rity Act;

1 “(B) family planning clinics;

2 “(C) rural health clinics;

3 “(D) Native entities, including Indian  
4 health programs as defined in section 4 of the  
5 Indian Health Care Improvement Act, urban  
6 Indian organizations as defined in section 4 of  
7 the Indian Health Care Improvement Act, and  
8 Native Hawaiian organizations as defined in  
9 section 12 of the Native Hawaiian Health Care  
10 Act of 1988;

11 “(E) community-based organizations, clin-  
12 ics, hospitals, and other health facilities that  
13 provide substance use disorder treatment serv-  
14 ices;

15 “(F) other nonprofit entities that provide  
16 substance use disorder treatment services; and

17 “(G) faith based organizations that provide  
18 substance use disorder treatment services.

19 “(2) UNDERSERVED POPULATIONS.—Entities  
20 described in paragraph (1) shall serve underserved  
21 populations which may include minority populations  
22 and Indian populations, ex-offenders, individuals  
23 with comorbidities including HIV/AIDS, hepatitis B  
24 or C, mental illness, or other behavioral health dis-

1 orders, low-income populations, inner city popu-  
2 lations, and rural populations.

3 “(3) APPLICATION.—To be eligible to receive a  
4 grant under this section, a public or nonprofit entity  
5 described in this subsection shall prepare and submit  
6 to the Secretary an application in such form, and  
7 containing such information, as the Secretary shall  
8 require, including—

9 “(A) a complete accounting of the dis-  
10 bursement of any prior grants received under  
11 this subtitle by the applicant and the results  
12 achieved by these expenditures;

13 “(B) a comprehensive plan for the use of  
14 the grant, including a demonstration of the ex-  
15 tent of local need for the funds sought and a  
16 plan for proposed substance use disorder treat-  
17 ment services that is consistent with local  
18 needs;

19 “(C) a demonstration that the grantee will  
20 use funds in a manner that provides substance  
21 use disorder treatment services compliant with  
22 the evidence-based standards developed in ac-  
23 cordance with section 3434, including all Feder-  
24 ally-approved medication-assisted treatments;

1           “(D) information on the number of individ-  
2 uals likely to be served by the funds sought, in-  
3 cluding demographic data on the populations to  
4 be served;

5           “(E) an identification of key outcomes that  
6 will be measured by all entities that receive as-  
7 sistance, as well as an explanation of how the  
8 outcomes will be measured;

9           “(F) a demonstration that resources pro-  
10 vided under the grant will be allocated in ac-  
11 cordance with the local demographic incidence  
12 of substance use, including allocations for serv-  
13 ices for children, youths, and women;

14           “(G) a demonstration that the confiden-  
15 tiality of individuals receiving substance use dis-  
16 order treatment services will be maintained in a  
17 manner not inconsistent with applicable law;  
18 and

19           “(H) an explanation of how income, asset,  
20 and medical expense criteria will be established  
21 and applied to those who qualify for assistance  
22 under the program.

23       “(c) REQUIREMENT OF STATUS AS MEDICAID PRO-  
24 VIDER.—

1           “(1) PROVISION OF SERVICE.—Subject to para-  
 2           graph (2), the Secretary may not make a grant  
 3           under this section for the provision of substance use  
 4           disorder treatment services under this section in a  
 5           State unless, in the case of any such service that is  
 6           available pursuant to the State plan approved under  
 7           title XIX of the Social Security Act for the State—

8                   “(A) the political subdivision involved will  
 9                   provide the substance use disorder treatment  
 10                  service directly, and the political subdivision has  
 11                  entered into a participation agreement under  
 12                  the State plan and is qualified to receive pay-  
 13                  ments under such plan; or

14                  “(B) the political subdivision involved will  
 15                  enter into an agreement with a public or non-  
 16                  profit private entity under which the entity will  
 17                  provide the substance use disorder treatment  
 18                  service, and the entity has entered into such a  
 19                  participation agreement and is qualified to re-  
 20                  ceive such payments.

21           “(2) WAIVER.—

22                   “(A) IN GENERAL.—In the case of an enti-  
 23                  ty making an agreement pursuant to paragraph  
 24                  (1)(B) regarding the provision of substance use  
 25                  disorder treatment services, the requirement es-

1           tablished in such paragraph shall be waived by  
2           the State if the entity does not, in providing  
3           such services, impose a charge or accept reim-  
4           bursement available from any third-party payor,  
5           including reimbursement under any insurance  
6           policy or under any Federal or State health  
7           benefits program.

8           “(B) DETERMINATION.—A determination  
9           by the State of whether an entity referred to in  
10          subparagraph (A) meets the criteria for a waiv-  
11          er under such subparagraph shall be made  
12          without regard to whether the entity accepts  
13          voluntary donations for the purpose of pro-  
14          viding services to the public.

15       “(d) AMOUNT OF GRANT TO NATIVE ENTITIES.—

16           “(1) INDIAN TRIBES.—In this section, the term  
17          ‘Indian tribe’ has the meaning given such term in  
18          section 4 of the Indian Self-Determination and Edu-  
19          cation Assistance Act.

20           “(2) FORMULA GRANTS.—The Secretary, acting  
21          through the Indian Health Service, shall use 10 per-  
22          cent of the amount available under section 3425 for  
23          each fiscal year to provide grants to Native entities  
24          in an amount determined pursuant to criteria devel-

1       oped by the Secretary in consultation with Indian  
2       tribes, for the purposes of addressing substance use.

3           “(3) USE OF AMOUNTS.—Notwithstanding any  
4       requirements in this section, Native entities may use  
5       amounts provided under grants awarded under this  
6       section for the uses identified in section 3422 and  
7       any other activities determined appropriate by the  
8       Secretary, in consultation with Indian tribes.

9       **“SEC. 3422. USE OF AMOUNTS.**

10       “(a) USE OF FUNDS.—An entity shall use amounts  
11       received under a grant under section 3421 to provide di-  
12       rect financial assistance to eligible entities for the purpose  
13       of delivering or enhancing—

14           “(1) prevention services described in subsection  
15       (b);

16           “(2) core medical services described in sub-  
17       section (c);

18           “(3) recovery and support services described in  
19       subsection (d);

20           “(4) early intervention and engagement services  
21       described in subsection (e);

22           “(5) harm reduction services described in sub-  
23       section (f); and

24           “(6) administrative expenses described in sub-  
25       section (g).

1       “(b) PREVENTION SERVICES.—For purposes of this  
 2 subsection, the term ‘prevention services’ means services,  
 3 programs, or multi-sector strategies to prevent substance  
 4 use disorder, including evidence-based education cam-  
 5 paigns, community-based prevention programs, opioid di-  
 6 version, collection and disposal of unused opioids, and  
 7 services to at-risk populations.

8       “(c) CORE MEDICAL SERVICES.—For purposes of  
 9 this section, the term ‘core medical services’ means the  
 10 following services when provided to individuals with sub-  
 11 stance use disorder or at risk for developing substance use  
 12 disorder:

13               “(1) Substance use disorder treatments, includ-  
 14 ing clinical stabilization services, withdrawal man-  
 15 agement and detoxification, intensive inpatient treat-  
 16 ment, intensive outpatient treatment, all forms of  
 17 Federally-approved medication-assisted treatment,  
 18 and residential recovery treatment.

19               “(2) Outpatient and ambulatory health services,  
 20 including those administered by federally qualified  
 21 health centers and rural health clinics.

22               “(3) Hospice services.

23               “(4) Mental health services.

24               “(5) Naloxone procurement, distribution, and  
 25 training.

1           “(6) Pharmaceutical assistance and diagnostic  
2           testing related to the management of substance-use  
3           disorder and co-morbid conditions.

4           “(7) Home and community based health serv-  
5           ices.

6           “(8) Comprehensive Case Management and care  
7           coordination, including treatment adherence services.

8           “(9) Health insurance enrollment and cost-  
9           sharing assistance in accordance with section 3412.

10          “(d) RECOVERY AND SUPPORT SERVICES.—For pur-  
11         poses of subsection (a)(3), the term ‘recovery and support  
12         services’ means services, subject to the approval of the  
13         Secretary, that are provided to individuals with substance  
14         use disorder, including residential recovery treatment and  
15         housing, including for individuals receiving medication-as-  
16         sisted treatment, long term recovery services, 24/7 hotline  
17         services, medical transportation services, respite care for  
18         persons caring for individuals with substance use disorder,  
19         child care and family services while an individual is receiv-  
20         ing inpatient treatment services or at the time of out-  
21         patient services, outreach services, peer recovery services,  
22         nutrition services, and referrals for job training and career  
23         services, housing, legal services, and child care and family  
24         services.

1       “(e) EARLY INTERVENTION AND ENGAGEMENT  
2 SERVICES.—For purposes of this section, the term ‘early  
3 intervention and engagement services’ means services to  
4 provide rapid access to substance use disorder treatment  
5 services, counseling provided to individuals who have mis-  
6 used substances, who have experienced an overdose, or are  
7 at risk of developing substance use disorder and the provi-  
8 sion of referrals to facilitate the access of such individuals  
9 to core medical services or recovery and support services.  
10 The entities through which such services may be provided  
11 include emergency rooms, fire departments and emergency  
12 medical services, detention facilities, homeless shelters,  
13 law enforcement agencies, health care points of entry spec-  
14 ified by eligible areas, Federally qualified health centers,  
15 and rural health clinics.

16       “(f) HARM REDUCTION SERVICES.—For purposes of  
17 this subsection, the term ‘harm reduction services’ means  
18 evidence-based services provided to individuals engaging in  
19 substance use that reduce the risk of infectious disease  
20 transmission, overdose, or death, including by increasing  
21 access to health care.

22       “(g) ADMINISTRATION AND PLANNING.—An entity  
23 shall not use in excess of 10 percent of amounts received  
24 under a grant under section 3421 for administration, ac-  
25 counting, reporting, and program oversight functions, in-

cluding for the purposes of developing systems to improve data collection and data sharing.

**“SEC. 3423. TECHNICAL ASSISTANCE.**

“The Secretary may, directly or through grants or contracts, provide technical assistance to nonprofit private entities and Native entities regarding the process of submitting to the Secretary applications for grants under section 3421, and may provide technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to such section.

**“SEC. 3424. PLANNING AND DEVELOPMENT GRANTS.**

“(a) IN GENERAL.—The Secretary may provide planning grants to public, nonprofit private, and Native entities for purposes of assisting such entities in expanding their capacity to provide substance use disorder treatment services in low-income communities and affected subpopulations that are underserved with respect to such services.

“(b) AMOUNT.—A grant under this section may be made in an amount not to exceed \$150,000.

**“SEC. 3425. AUTHORIZATION OF APPROPRIATIONS.**

“There is authorized to be appropriated to carry out this subtitle—

“(1) \$500,000,000 for fiscal year 2019;

“(2) \$500,000,000 for fiscal year 2020;

- 1 “(3) \$500,000,000 for fiscal year 2021;  
 2 “(4) \$500,000,000 for fiscal year 2022;  
 3 “(5) \$500,000,000 for fiscal year 2023;  
 4 “(6) \$500,000,000 for fiscal year 2024;  
 5 “(7) \$500,000,000 for fiscal year 2025;  
 6 “(8) \$500,000,000 for fiscal year 2026;  
 7 “(9) \$500,000,000 for fiscal year 2027; and  
 8 “(10) \$500,000,000 for fiscal year 2028.

9 **“Subtitle D—Miscellaneous**  
 10 **Provisions**

11 **“SEC. 3431. SPECIAL PROJECTS OF NATIONAL SIGNIFI-**  
 12 **CANCE.**

13 “(a) IN GENERAL.—The Secretary, acting in con-  
 14 sultation with the Director of the Office of National Drug  
 15 Control Policy, shall award grants to entities to administer  
 16 special projects of national significance to support the de-  
 17 velopment of innovative and original models for the deliv-  
 18 ery of substance use disorder treatment services.

19 “(b) GRANTS.—The Secretary shall award grants  
 20 under a project under subsection (a) to entities eligible  
 21 for grants under subtitles A, B, and C based on newly  
 22 emerging needs of individuals receiving assistance under  
 23 this title.

24 “(c) REPLICATION.—The Secretary shall make infor-  
 25 mation concerning successful models or programs devel-

1 oped under this section available to grantees under this  
 2 title for the purpose of coordination, replication, and inte-  
 3 gration. To facilitate efforts under this subsection, the  
 4 Secretary may provide for peer-based technical assistance  
 5 for grantees funded under this section.

6 “(d) GRANTS TO TRIBAL GOVERNMENTS.—

7 “(1) INDIAN TRIBES.—In this section, the term  
 8 ‘Indian tribe’ has the meaning given such term in  
 9 section 4 of the Indian Self-Determination and Edu-  
 10 cation Assistance Act.

11 “(2) USE OF FUNDS.—The Secretary, acting  
 12 through the Indian Health Service, shall use 10 per-  
 13 cent of the amount available under this section for  
 14 each fiscal year to provide grants to Indian tribes  
 15 for the purposes of supporting the development of  
 16 innovative and original models for the delivery of  
 17 substance use disorder treatment and services, in-  
 18 cluding the development of culturally-informed care  
 19 models.

20 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
 21 is authorized to be appropriated to carry out this section—

22 “(1) \$500,000,000 for fiscal year 2019;

23 “(2) \$500,000,000 for fiscal year 2020;

24 “(3) \$500,000,000 for fiscal year 2021;

25 “(4) \$500,000,000 for fiscal year 2022;

- 1 “(5) \$500,000,000 for fiscal year 2023;  
 2 “(6) \$500,000,000 for fiscal year 2024;  
 3 “(7) \$500,000,000 for fiscal year 2025;  
 4 “(8) \$500,000,000 for fiscal year 2026;  
 5 “(9) \$500,000,000 for fiscal year 2027; and  
 6 “(10) \$500,000,000 for fiscal year 2028.

7 **“SEC. 3432. EDUCATION AND TRAINING CENTERS.**

8 “(a) IN GENERAL.—The Secretary may make grants  
 9 and enter into contracts to assist public and nonprofit pri-  
 10 vate entities, and schools, and academic health centers in  
 11 meeting the cost of projects—

12 “(1) to train health personnel, including practi-  
 13 tioners in programs under this title and other com-  
 14 munity providers, including counselors, case man-  
 15 agers, social workers, peer recovery coaches, and  
 16 harm reduction workers, in the diagnosis, treatment,  
 17 and prevention of substance use disorders, including  
 18 measures for the prevention and treatment of co-oc-  
 19 ccurring infectious diseases and other conditions, and  
 20 including (as applicable to the type of health profes-  
 21 sional involved), care for women, pregnant women,  
 22 and children;

23 “(2) to train the faculty of schools of medicine,  
 24 nursing, public health, osteopathic medicine, den-  
 25 tistry, allied health, and mental health practice to

1 teach health professions students to screen for and  
 2 provide for the needs of individuals with substance  
 3 use disorders or at risk of substance use; and

4 “(3) to develop and disseminate curricula and  
 5 resource materials relating to evidence-based prac-  
 6 tices for the screening, prevention, and treatment of  
 7 substance use disorders, including information about  
 8 prescribing best practices, alternative pain therapies,  
 9 and Federally-approved medication-assisted treat-  
 10 ment options.

11 “(b) PREFERENCE IN MAKING GRANTS.—In making  
 12 grants under subsection (a), the Secretary shall give pref-  
 13 erence to qualified projects that will—

14 “(1) train, or result in the training of, health  
 15 professionals, including counselors, case managers,  
 16 social workers, peer recovery coaches, and harm re-  
 17 duction workers, who will provide substance use dis-  
 18 order treatments for underserved groups, including  
 19 minority individuals and Indians with substance use  
 20 disorder and other individuals who are at a high risk  
 21 of substance use;

22 “(2) train, or result in the training of, minority  
 23 health professionals and minority allied health pro-  
 24 fessionals, including counselors, case managers, so-  
 25 cial workers, peer recovery coaches, and harm reduc-

1       tion workers, to provide substance use disorder  
2       treatment for individuals with such disease;

3               “(3) train or result in the training of individ-  
4       uals, including counselors, case managers, social  
5       workers, peer recovery coaches, and harm reduction  
6       workers, who will provide substance use disorder  
7       treatment in rural or other areas that are under-  
8       served by current treatment structures; and

9               “(4) train or result in the training of health  
10      professionals and allied health professionals, includ-  
11      ing counselors, case managers, social workers, peer  
12      recovery coaches, and harm reduction workers, to  
13      provide treatment for infectious diseases and mental  
14      health conditions co-occurring with substance use  
15      disorder.

16      “(c) NATIVE EDUCATION AND TRAINING CEN-  
17      TERS.—The Secretary shall use 10 percent of the amount  
18      available under subsection (d) for each fiscal year to pro-  
19      vide grants authorized under this subtitle to—

20              “(1) tribal colleges and universities;

21              “(2) Indian Health Service grant funded insti-  
22      tutions; and

23              “(3) Native partner institutions, including insti-  
24      tutions of higher education with medical training  
25      programs that partner with one or more Indian

1 tribes, tribal organizations, Native Hawaiian organi-  
 2 zations, or tribal colleges and universities to train  
 3 Native health professionals that will provide sub-  
 4 stance use disorder treatment services in Native  
 5 communities.

6 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
 7 is authorized to be appropriated to carry out this section—

8 “(1) \$400,000,000 for fiscal year 2019;

9 “(2) \$400,000,000 for fiscal year 2020;

10 “(3) \$400,000,000 for fiscal year 2021;

11 “(4) \$400,000,000 for fiscal year 2022;

12 “(5) \$400,000,000 for fiscal year 2023;

13 “(6) \$400,000,000 for fiscal year 2024;

14 “(7) \$400,000,000 for fiscal year 2025;

15 “(8) \$400,000,000 for fiscal year 2026;

16 “(9) \$400,000,000 for fiscal year 2027; and

17 “(10) \$400,000,000 for fiscal year 2028.

18 **“SEC. 3433. OTHER PROVISIONS.**

19 “(a) MEDICATION-ASSISTED TREATMENT.—The Sec-  
 20 retary may not make a grant under this title unless the  
 21 applicant for the grant agrees to require all entities offer-  
 22 ing substance use disorder treatment services under the  
 23 grant to offer all Federally-approved forms of medication-  
 24 assisted substance use treatment for the substance use  
 25 disorders for which the applicant offers treatment.

1       “(b) WAIVER.—The Secretary may grant a waiver  
2 with respect to any requirement of this title if the grant  
3 applicant involved—

4           “(1) submits to the Secretary a justification  
5 containing such information as the Secretary shall  
6 require; and

7           “(2) agrees to require all entities offering sub-  
8 stance use disorder treatment services under the  
9 grant—

10           “(A) to offer at least two Federally-ap-  
11 proved forms of medication-assisted treatment  
12 on site;

13           “(B) provide counseling to patients on the  
14 benefits and risks of all forms of Federally-ap-  
15 proved medication-assisted treatments; and

16           “(C) maintain an affiliation with a pro-  
17 vider that can prescribe or otherwise dispense  
18 all other forms of Federally-approved medica-  
19 tion-assisted treatment.

20       “(c) GAO STUDY.—Not later than 1 year after the  
21 date of enactment of this title, the Comptroller General  
22 of the United States shall submit to Congress a com-  
23 prehensive report describing any relationship between sub-  
24 stance use rates, pain management practices of the Indian  
25 Health Service, and patient request denials through the

1 purchased/referred care program of the Indian Health  
2 Service.

3 **“SEC. 3434. STANDARDS FOR SUBSTANCE USE DISORDER**  
4 **TREATMENT AND RECOVERY FACILITIES.**

5 “(a) IN GENERAL.—Not later than 3 years after the  
6 date of enactment of this title, the Secretary, in consulta-  
7 tion with the American Society of Addiction Medicine,  
8 shall promulgate model standards for the regulation of  
9 substance use disorder treatment services.

10 “(b) CONTENTS.—The model standards promulgated  
11 under subsection (a) shall—

12 “(1) identify the types of providers intended to  
13 be covered without regard to whether such providers  
14 participate in any Federal health care program (as  
15 defined in section 1128B(f) of the Social Security  
16 Act (42 U.S.C. 1320a–7b(f))) and shall not include  
17 a private practitioner who is already licensed by a  
18 State medical licensing board and whose practice is  
19 limited to outpatient care;

20 “(2) require that all substance use disorder  
21 treatment services be licensed by the respective  
22 States for the levels of care which they provide;

23 “(3) identify the professional credentials needed  
24 by each type of substance use disorder treatment  
25 professional;

1           “(4) require that patients have access to li-  
2           censed substance use disorder treatment services, in-  
3           cluding health care providers and physicians, for in-  
4           patient and outpatient care;

5           “(5) identify and develop strategies for States  
6           to ensure that all substance use disorder patients re-  
7           ceive a medical assessment, including for co-occur-  
8           ring mental health issues and infectious diseases;

9           “(6) require States to implement a process to  
10          ensure that residential treatment provider qualifica-  
11          tions are verified by the single State agency serving  
12          as the primary regulator in the State for substance  
13          use disorder treatment services (as required in para-  
14          graph (13)) or by an independent third party with  
15          the necessary competencies to use evidence-based pa-  
16          tient placement assessment tools and nationally-rec-  
17          ognized program standards, as applicable;

18          “(7) ensure that patients receiving substance  
19          use disorder treatment have access directly, by refer-  
20          ral, or in such other manner as determined by the  
21          Secretary, to all Federally-approved medication-as-  
22          sisted treatments for substance use disorder;

23          “(8) develop standards for data reporting and  
24          require compilation of Statewide reports;

1           “(9) develop standards for licensed providers to  
2       ensure all patients receive an outpatient treatment  
3       and discharge plan;

4           “(10) develop standards for the certification of  
5       recovery residences that have an ongoing economic  
6       relationship with any commercial substance use dis-  
7       order treatment service, including any relationship  
8       with any such service that includes receiving or mak-  
9       ing referrals for substance use disorder treatment,  
10      including—

11           “(A) application, inspection, and renewal  
12      procedures for recovery residences;

13           “(B) fire, safety, and health standards;

14           “(C) standards for equipping residences  
15      with naloxone and training residence owners,  
16      operators, and employees in the administration  
17      of naloxone;

18           “(D) standards for recovery residence own-  
19      ers and operators; and

20           “(E) standards to identify, disqualify from  
21      grant funding, and refer to the appropriate reg-  
22      ulatory authority any entity engaged in the so-  
23      liciting or receiving of a commission, benefit,  
24      bonus, rebate, kickback, or bribe, directly or in-  
25      directly, in cash or in kind, or engaging in any

1 split-fee arrangement, aimed at inducing the re-  
2 ferral of a patient to or from a substance use  
3 disorder treatment service;

4 “(11) establish a toll-free telephone number to  
5 handle complaints about recovery residences;

6 “(12) establish and maintain on a publicly ac-  
7 cessible internet website a list of all recovery resi-  
8 dences in the State that have a certification in effect  
9 in accordance with this section;

10 “(13) require the designation of a single State  
11 agency to serve as the primary regulator in the  
12 State for substance use disorder treatment services;

13 “(14) require a single State agency to imple-  
14 ment a process to ensure that treatment provider as-  
15 sessments for all substance use disorder treatment  
16 services, including levels of care and length-of-stay  
17 recommendations, are verified by an independent  
18 third party that has the necessary competencies to  
19 use evidence-based patient placement assessment  
20 tools and nationally-recognized program standards,  
21 as applicable; and

22 “(15) consider existing barriers to substance  
23 use disorder treatment and service access, including  
24 capacity and infrastructure needs, as well as access  
25 to culturally attuned services.

1       “(c) ANNUAL ASSESSMENT.—Beginning with respect  
 2 to fiscal year 2021, the Secretary shall make a determina-  
 3 tion with respect to each State on whether the State has  
 4 adopted the model standards promulgated in accordance  
 5 with this section.

6       “(d) QUALITY MEASURES.—The Secretary shall en-  
 7 gage a nonprofit, non-partisan standards development and  
 8 quality measurement organization to convene government  
 9 regulators, State representatives, consumer representa-  
 10 tives, substance use disorder treatment providers, recovery  
 11 residence owners and operators, and purchasers of sub-  
 12 stance use disorder treatments exercising leadership in  
 13 quality-based purchasing to develop and annually revise  
 14 a set of health care quality measures for substance use  
 15 disorder treatment providers and owners and operators of  
 16 recovery residences.

17 **“SEC. 3435. NALOXONE DISTRIBUTION PROGRAM.**

18       “(a) ESTABLISHMENT OF PROGRAM.—

19               “(1) IN GENERAL.—The Secretary shall provide  
 20 for the purchase and delivery of Federally-approved  
 21 opioid overdose reversal drug products on behalf of  
 22 each State (or Indian tribe as defined in section 4  
 23 of the Indian Health Care Improvement Act) that  
 24 receives a grant under subtitle B. This paragraph  
 25 constitutes budget authority in advance of appro-

1        priations Acts, and represents the obligation of the  
2        Federal Government to provide for the purchase and  
3        delivery to States of the opioid overdose reversal  
4        drug products in accordance with this paragraph.

5            “(2) SPECIAL RULES WHERE OPIOID OVERDOSE  
6        REVERSAL DRUG PRODUCTS ARE UNAVAILABLE.—To  
7        the extent that a sufficient quantity of opioid over-  
8        dose reversal drug products are not available for  
9        purchase or delivery under paragraph (1), the Sec-  
10       retary shall provide for the purchase and delivery of  
11       the available opioid overdose reversal drug products  
12       in accordance with priorities established by the Sec-  
13       retary, with priority given to States with at least one  
14       local area eligible for funding under section 3401(a).

15           “(b) NEGOTIATION OF CONTRACTS WITH MANUFAC-  
16       TURERS.—

17           “(1) IN GENERAL.—For the purpose of car-  
18       rying out this section, the Secretary shall negotiate  
19       and enter into contracts with manufacturers of  
20       opioid overdose reversal drug products consistent  
21       with the requirements of this subsection and, to the  
22       maximum extent practicable, consolidate such con-  
23       tracting with any other contracting activities con-  
24       ducted by the Secretary to purchase opioid overdose  
25       reversal drug products. The Secretary may enter

1 into such contracts under which the Federal Govern-  
 2 ment is obligated to make outlays, the budget au-  
 3 thority for which is not provided for in advance in  
 4 appropriations Acts, for the purchase and delivery of  
 5 opioid overdose reversal drug products under sub-  
 6 section (a).

7 “(2) AUTHORITY TO DECLINE CONTRACTS.—

8 The Secretary may decline to enter into contracts  
 9 under this subsection and may modify or extend  
 10 such contracts.

11 “(3) CONTRACT PRICE.—

12 “(A) IN GENERAL.—The Secretary, in ne-  
 13 gotiating the prices at which opioid overdose re-  
 14 versal drug products will be purchased and de-  
 15 livered from a manufacturer under this sub-  
 16 section, shall take into account quantities of  
 17 opioid overdose reversal drug products to be  
 18 purchased by States under the option under  
 19 paragraph (4)(B).

20 “(B) NEGOTIATION OF DISCOUNTED PRICE  
 21 FOR OPIOID OVERDOSE REVERSAL DRUG PROD-  
 22 UCTS.—With respect to contracts entered into  
 23 for the purchase of opioid overdose reversal  
 24 drug products on behalf of States under this  
 25 subsection, the price for the purchase of such

1 drug product shall be a discounted price nego-  
2 tiated by the Secretary.

3 “(4) PRODUCT DOSAGE.—All opioid overdose  
4 reversal products purchased under this section shall  
5 contain—

6 “(A) for each dose, the maximum amount  
7 of active pharmaceutical ingredient that acts as  
8 an opioid receptor antagonist as recommended  
9 by the Food and Drug Administration as an  
10 initial dose when administered by one of the ap-  
11 proved, labeled routes of administration in  
12 adults; and

13 “(B) a minimum of two doses packaged to-  
14 gether.

15 “(5) QUANTITIES AND TERMS OF DELIVERY.—  
16 Under contracts under this subsection—

17 “(A) the Secretary shall provide, consistent  
18 with paragraph (6), for the purchase and deliv-  
19 ery on behalf of States and Indian tribes of  
20 quantities of opioid overdose reversal drug  
21 products; and

22 “(B) each State and Indian tribe, at the  
23 option of the State or tribe, shall be permitted  
24 to obtain additional quantities of opioid over-  
25 dose reversal drug products (subject to amounts

1 specified to the Secretary by the State or tribe  
2 in advance of negotiations) through purchasing  
3 the opioid overdose reversal drug products from  
4 the manufacturers at the applicable price nego-  
5 tiated by the Secretary consistent with para-  
6 graph (3), if the State or tribe provides to the  
7 Secretary such information (at a time and man-  
8 ner specified by the Secretary, including in ad-  
9 vance of negotiations under paragraph (1)) as  
10 the Secretary determines to be necessary, to  
11 provide for quantities of opioid overdose rever-  
12 sal drug products for the State or tribe to pur-  
13 chase pursuant to this subsection and to deter-  
14 mine annually the percentage of the opioid over-  
15 dose reversal drug market that is purchased  
16 pursuant to this section and this subparagraph.

17 The Secretary shall enter into the initial negotia-  
18 tions not later than 180 days after the date of the  
19 enactment of this title.

20 “(6) CHARGES FOR SHIPPING AND HAN-  
21 DLING.—The Secretary may enter into a contract  
22 referred to in paragraph (1) only if the manufac-  
23 turer involved agrees to submit to the Secretary  
24 such reports as the Secretary determines to be ap-  
25 propriate to assure compliance with the contract and

1 if, with respect to a State program under this sec-  
2 tion that does not provide for the direct delivery of  
3 qualified opioid overdose reversal drug products, the  
4 manufacturer involved agrees that the manufacturer  
5 will provide for the delivery of the opioid overdose  
6 reversal drug products on behalf of the State in ac-  
7 cordance with such program and will not impose any  
8 charges for the costs of such delivery (except to the  
9 extent such costs are provided for in the price estab-  
10 lished under paragraph (3)).

11 “(7) MULTIPLE SUPPLIERS.—In the case of the  
12 opioid overdose reversal drug product involved, the  
13 Secretary may, as appropriate, enter into a contract  
14 referred to in paragraph (1) with each manufacturer  
15 of the opioid overdose reversal drug product that  
16 meets the terms and conditions of the Secretary for  
17 an award of such a contract (including terms and  
18 conditions regarding safety and quality). With re-  
19 spect to multiple contracts entered into pursuant to  
20 this paragraph, the Secretary may have in effect dif-  
21 ferent prices under each of such contracts and, with  
22 respect to a purchase by States pursuant to para-  
23 graph (4)(B), each eligible State may choose which  
24 of such contracts will be applicable to the purchase.

1       “(c) USE OF OPIOID OVERDOSE REVERSAL DRUG  
 2 PRODUCT LIST.—Beginning not later than one year after  
 3 the first contract has been entered into under this section,  
 4 the Secretary shall use, for the purpose of the purchase,  
 5 delivery, and administration of opioid overdose reversal  
 6 drug products under this section, the list established (and  
 7 periodically reviewed and, as appropriate, revised) by an  
 8 advisory committee, established by the Secretary and lo-  
 9 cated within the Centers for Disease Control and Preven-  
 10 tion, which considers the cost effectiveness of each opioid  
 11 overdose reversal drug product.

12       “(d) STATE DISTRIBUTION OF OPIOID OVERDOSE  
 13 REVERSAL DRUG PRODUCTS.—States shall distribute  
 14 opioid overdose reversal drug products received under this  
 15 section to the following:

16               “(1) First Responders, including—

17                       “(A) all State, county, and local law en-  
 18                       forcement departments;

19                       “(B) all Tribal police departments;

20                       “(C) all local fire departments, including  
 21                       career fire departments, combination fire de-  
 22                       partments, and volunteer fire departments; and

23                       “(D) all local emergency medical services  
 24                       organizations, including volunteer emergency  
 25                       medical services organizations.

1           “(2) Public entities with authority to administer  
2           local public health services, including all local health  
3           departments, for the purposes of making opioid over-  
4           dose reversal drug products available to—

5                   “(A) public and nonprofit entities, includ-  
6           ing—

7                           “(i) community-based organizations  
8                           that provide substance use disorder treat-  
9                           ments or harm reduction services;

10                           “(ii) nonprofit entities that provide  
11                           substance use disorder treatments or harm  
12                           reduction services; and

13                           “(iii) faith based organizations that  
14                           provide substance use disorder treatments  
15                           or harm reduction services; and

16                           “(B) the general public.

17           “(e) STATE REQUIREMENTS.—To be eligible to re-  
18           ceive opioid overdose reversal drugs under this section,  
19           each State shall—

20                   “(1) establish a program for distributing opioid  
21                   overdose reversal drug products to first responders  
22                   and entities with authority to administer local public  
23                   health services, including local health departments;

24                   “(2) beginning in the second year of the pro-  
25                   gram, demonstrate a distribution rate of a minimum

1 of 90 percent of the opioid overdose reversal drug  
 2 products received under this program; and

3 “(3) certify to the Secretary that the State has  
 4 in place measures that enhance access to opioid  
 5 overdose reversal drug products, such as laws that  
 6 provide civil or disciplinary immunity for medical  
 7 personnel who prescribe an opioid overdose reversal  
 8 drug product, Good Samaritan Laws, Third Party  
 9 Prescription Laws, Collaborative Practice Agree-  
 10 ments, and Standing Orders.

11 “(f) INDIAN TRIBE REQUIREMENTS.—The Indian  
 12 Health Service, in consultation with Indian tribes, shall  
 13 determine any requirements that shall apply to Indian  
 14 tribes receiving opioid overdose reversal drug products  
 15 made available under this section.

16 “(g) DEFINITIONS.—For purposes of this section:

17 “(1) CAREER FIRE DEPARTMENT.—The term  
 18 ‘career fire department’ means a fire department  
 19 that has an all-paid force of firefighting personnel  
 20 other than paid-on-call firefighters.

21 “(2) COLLABORATIVE PRACTICE AGREEMENT.—  
 22 The term ‘Collaborative Practice Agreement’ means  
 23 an agreement under which a pharmacist operates  
 24 under authority delegated by another licensed practi-  
 25 tioner with prescribing authority.

1           “(3) COMBINATION FIRE DEPARTMENT.—The  
2           term ‘combination fire department’ means a fire de-  
3           partment that has paid firefighting personnel and  
4           volunteer firefighting personnel.

5           “(4) EMERGENCY MEDICAL SERVICE.—The  
6           term ‘emergency medical service’ means resources  
7           used by a public or private nonprofit licensed entity  
8           to deliver medical care outside of a medical facility  
9           under emergency conditions that occur as a result of  
10          the condition of the patient and includes services de-  
11          livered (either on a compensated or volunteer basis)  
12          by an emergency medical services provider or other  
13          provider that is licensed or certified by the State in-  
14          volved as an emergency medical technician, a para-  
15          medic, or an equivalent professional (as determined  
16          by the State).

17          “(5) GOOD SAMARITAN LAW.—The term ‘Good  
18          Samaritan Law’ means a law that provides criminal  
19          immunity for a person who administers an opioid  
20          overdose reversal drug product, a person who, in  
21          good faith, seeks medical assistance for someone ex-  
22          periencing a drug-related overdose, or a person who  
23          experiences a drug-related overdose and is in need of  
24          medical assistance and, in good faith, seeks such

1 medical assistance, or is the subject of such a good  
2 faith request for medical assistance.

3 “(6) INDIANS.—The terms ‘Indian’, ‘Indian  
4 tribe’, ‘tribal organization’, and ‘Urban Indian  
5 Health Program’ have the meanings given such  
6 terms in section 4 of the Indian Health Care Im-  
7 provement Act.

8 “(7) MANUFACTURER.—The term ‘manufac-  
9 turer’ means any corporation, organization, or insti-  
10 tution, whether public or private (including Federal,  
11 State, and local departments, agencies, and instru-  
12 mentalities), which manufactures, imports, proc-  
13 esses, or distributes under its label any opioid over-  
14 dose reversal drug product. The term ‘manufacture’  
15 means to manufacture, import, process, or distribute  
16 an opioid overdose reversal drug.

17 “(8) OPIOID OVERDOSE REVERSAL DRUG PROD-  
18 UCT.—The term ‘opioid overdose reversal drug prod-  
19 uct’ means a finished dosage form that has been ap-  
20 proved by the Food and Drug Administration and  
21 that contains an active pharmaceutical ingredient  
22 that acts as an opioid receptor antagonist. The term  
23 ‘opioid overdose reversal drug product’ includes a  
24 combination product, as defined in section 3.2(e) of  
25 title 21, Code of Federal Regulations.

1           “(9) STANDING ORDER.—The term ‘standing  
2           order’ means a non-patient-specific order covering  
3           administration of medication by others to a patient  
4           who may be unknown to the prescriber at the time  
5           of the order.

6           “(10) THIRD PARTY PRESCRIPTION.—The term  
7           ‘third party prescription’ means an order written for  
8           medication dispensed to one person with the inten-  
9           tion that it will be administered to another person.

10          “(11) VOLUNTEER FIRE DEPARTMENT.—The  
11          term ‘volunteer fire department’ means a fire de-  
12          partment that has an all-volunteer force of fire-  
13          fighting personnel.

14          “(h) AUTHORIZATION OF APPROPRIATIONS.—There  
15          is authorized to be appropriated to carry out this suc-  
16          tion—

17               “(1) \$500,000,000 for fiscal year 2019;

18               “(2) \$500,000,000 for fiscal year 2020;

19               “(3) \$500,000,000 for fiscal year 2021;

20               “(4) \$500,000,000 for fiscal year 2022;

21               “(5) \$500,000,000 for fiscal year 2023;

22               “(6) \$500,000,000 for fiscal year 2024;

23               “(7) \$500,000,000 for fiscal year 2025;

24               “(8) \$500,000,000 for fiscal year 2026;

25               “(9) \$500,000,000 for fiscal year 2027; and

1 “(10) \$500,000,000 for fiscal year 2028.

2 **“SEC. 3436. ADDITIONAL FUNDING FOR THE NATIONAL IN-**  
 3 **STITUTES OF HEALTH.**

4 “There is authorized to be appropriated to the Na-  
 5 tional Institute of Health for the purpose of conducting  
 6 research on addiction and pain related to substance mis-  
 7 use, including research to develop overdose reversal drug  
 8 products, non-addictive drug products for treating pain,  
 9 and drug products used to treat substance use disorder—

10 “(1) \$1,000,000,000 for fiscal year 2019;

11 “(2) \$1,000,000,000 for fiscal year 2020;

12 “(3) \$1,000,000,000 for fiscal year 2021;

13 “(4) \$1,000,000,000 for fiscal year 2022;

14 “(5) \$1,000,000,000 for fiscal year 2023;

15 “(6) \$1,000,000,000 for fiscal year 2024;

16 “(7) \$1,000,000,000 for fiscal year 2025;

17 “(8) \$1,000,000,000 for fiscal year 2026;

18 “(9) \$1,000,000,000 for fiscal year 2027; and

19 “(10) \$1,000,000,000 for fiscal year 2028.

20 **“SEC. 3437. ADDITIONAL FUNDING FOR IMPROVED DATA**  
 21 **COLLECTION AND PREVENTION OF INFEC-**  
 22 **TIOUS DISEASE TRANSMISSION.**

23 “(a) DATA COLLECTION.—The Centers for Disease  
 24 Control and Prevention shall use a portion of the funding  
 25 appropriated under this section to ensure that all States

1 participate in the Enhanced State Opioid Overdose Sur-  
2veillance program and to provide technical assistance to  
3 medical examiners and coroners to facilitate improved  
4 data collection on fatal overdoses through such program.

5 “(b) CENTERS FOR DISEASE CONTROL AND PREVEN-  
6TION.—The Centers for Disease Control and Prevention  
7 shall use amounts appropriated under this section for the  
8 purpose of improving data on drug overdose deaths and  
9 non-fatal drug overdoses, surveillance related to addiction  
10 and substance use disorder, and the prevention of trans-  
11 mission of infectious diseases related to substance use.

12 “(c) TRIBAL EPIDEMIOLOGY CENTERS.—There shall  
13 be made available to the Indian Health Service for the  
14 purpose of funding efforts by tribal epidemiology centers  
15 to improve data on drug overdose deaths and non-fatal  
16 drug overdoses and surveillance related to addiction and  
17 substance use disorder, not less than 1.5 percent of the  
18 total amount appropriated under this section for each fis-  
19 cal year.

20 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
21 is authorized to be appropriated to carry out this section—

22 “(1) \$400,000,000 for fiscal year 2019;

23 “(2) \$400,000,000 for fiscal year 2020;

24 “(3) \$400,000,000 for fiscal year 2021;

25 “(4) \$400,000,000 for fiscal year 2022;

- 1 “(5) \$400,000,000 for fiscal year 2023;  
2 “(6) \$400,000,000 for fiscal year 2024;  
3 “(7) \$400,000,000 for fiscal year 2025;  
4 “(8) \$400,000,000 for fiscal year 2026;  
5 “(9) \$400,000,000 for fiscal year 2027; and  
6 “(10) \$400,000,000 for fiscal year 2028.

7 **“SEC. 3438. DEFINITIONS.**

8 “In this title:

9 “(1) PLANNING COUNCIL.—The term ‘planning  
10 council’ means the substance use planning council  
11 established under section 3402.

12 “(2) RECOVERY RESIDENCE.—The term ‘recov-  
13 ery residence’ means a residential dwelling unit, or  
14 other form of group housing, that is offered or ad-  
15 vertised through any means, including oral, written,  
16 electronic, or printed means, by any individual or en-  
17 tity as a residence that provides an evidence-based,  
18 peer-supported living environment for individuals un-  
19 dergoing any type of substance use disorder treat-  
20 ment or who have received any type of substance use  
21 disorder treatment in the past 3 years, including  
22 medication-assisted treatment.

23 “(3) STATE.—

1           “(A) IN GENERAL.—The term ‘State’  
2           means each of the 50 States, the District of Co-  
3           lumbia, and each of the territories.

4           “(B) TERRITORIES.—The term ‘territory’  
5           means each of American Samoa, Guam, the  
6           Commonwealth of Puerto Rico, the Common-  
7           wealth of the Northern Mariana Islands, the  
8           Virgin Islands, the Republic of the Marshall Is-  
9           lands, the Federated States of Micronesia, and  
10          Palau.

11          “(4) SUBSTANCE USE DISORDER TREAT-  
12          MENT.—

13               “(A) IN GENERAL.—The term ‘substance  
14               use disorder treatment’ means an evidence-  
15               based, professionally directed, deliberate, and  
16               planned regimen including evaluation, observa-  
17               tion, medical monitoring, and rehabilitative  
18               services and interventions such as  
19               pharmacotherapy, behavioral therapy, and indi-  
20               vidual and group counseling, on an inpatient or  
21               outpatient basis, to help patients with substance  
22               use disorder reach recovery.

23               “(B) TYPES OF TREATMENT.—Substance  
24               use disorder treatments shall include the fol-  
25               lowing:

1           “(i) Clinical stabilization services,  
 2           which are evidence-based services provided  
 3           in secure, acute care facilities (which may  
 4           be referred to as ‘addictions receiving fa-  
 5           cilities’) that, at a minimum—

6                       “(I) provide detoxification and  
 7                       stabilization services;

8                       “(II) are operated 24 hours per  
 9                       day, 7 days per week; and

10                      “(III) that serve individuals  
 11                      found to be substance use impaired.  
 12                      These can also be referred to as ‘Ad-  
 13                      dictions receiving facilities’.

14                      “(ii) Withdrawal management and de-  
 15                      toxification, which is a service that is pro-  
 16                      vided on an inpatient or an outpatient  
 17                      basis to assist individuals manage the  
 18                      process of withdrawing from the physio-  
 19                      logical and psychological effects of sub-  
 20                      stance use disorder.

21                      “(iii) Intensive inpatient treatment,  
 22                      which is a service that provides a planned  
 23                      regimen of evidence-based evaluation, ob-  
 24                      servation, medical monitoring, and evi-  
 25                      dence-based rehabilitative services and

1 interventions such as pharmacotherapy, be-  
2 havioral therapy, and counseling, 24 hours  
3 per day, 7 days per week, in a highly  
4 structured, residential environment.

5 “(iv) Intensive outpatient treatment,  
6 which is a service that provides a planned  
7 regimen of evidence-based evaluation, ob-  
8 servation, medical monitoring, and evi-  
9 dence-based rehabilitative services and  
10 interventions such as pharmacotherapy, be-  
11 havioral therapy, and counseling, in a  
12 structured, nonresidential environment at a  
13 higher level of intensity and duration than  
14 outpatient treatment.

15 “(v) Medication-assisted treatment,  
16 which is a service that uses Federally-ap-  
17 proved medication as authorized by Fed-  
18 eral and State law, in combination with  
19 evidence-based medical, rehabilitative, and  
20 counseling services, in the treatment of in-  
21 dividuals who suffer from substance use  
22 disorder.

23 “(vi) Outpatient treatment, which is a  
24 service that provides a planned regimen of  
25 evidence-based evaluation, observation,

1 medical monitoring, and evidence-based re-  
 2 habilitative services and interventions such  
 3 as pharmacotherapy, behavioral therapy,  
 4 and counseling in a structured, nonresiden-  
 5 tial environment by appointment during  
 6 scheduled operating hours.

7 “(vii) Residential recovery treatment,  
 8 which is a service that provides a planned  
 9 regimen of evidence-based evaluation, ob-  
 10 servation, medical monitoring, and evi-  
 11 dence-based rehabilitative services and  
 12 interventions such as pharmacotherapy, be-  
 13 havioral therapy, and counseling provided  
 14 in a structured, live-in environment within  
 15 a nonhospital setting on a 24-hours-per-  
 16 day, 7-days-per-week basis.

17 “(C) LIMITATION.—Substance use disorder  
 18 treatment providers shall not include—

19 “(i) prevention only providers; and

20 “(ii) a private practitioner who is li-  
 21 censed by a State medical licensing board  
 22 and whose practice is limited to outpatient  
 23 care.

24 “(5) SUBSTANCE USE DISORDER TREATMENT  
 25 SERVICES.—The term ‘substance use disorder treat-

1       ment services’ means any prevention services, core  
 2       medical services, recovery and support services, early  
 3       intervention and engagement services, and harm re-  
 4       duction services authorized under this title.”.

5   **SEC. 4. AMENDMENTS TO THE CONTROLLED SUBSTANCES**  
 6                   **ACT.**

7       (a) CERTIFICATIONS.—Part C of the Controlled Sub-  
 8       stances Act (21 U.S.C. 821 et seq.) is amended by adding  
 9       at the end the following:

10      “CERTIFICATIONS RELATING TO DIVERSION CONTROLS  
 11                                   AND MISBRANDING

12      “SEC. 312. (a) DEFINITIONS.—In this section—

13                   “(1) the term ‘covered dispenser’—

14                                   “(A) means a dispenser—

15   “(i) that is required to register under  
 16   section 302(a)(2); and

17   “(ii) dispenses a controlled substance  
 18   in schedule II; and

19                                   “(B) does not include a dispenser that is—

20   “(i) registered to dispense opioid  
 21   agonist treatment medication under section  
 22   303(g)(1); and

23   “(ii) operating in that capacity;

24                   “(2) the term ‘covered distributor’ means a dis-  
 25       tributor—

1           “(A) that is required to register under sec-  
2           tion 302(a)(1); and

3           “(B) distributes a controlled substance in  
4           schedule II;

5           “(3) the term ‘covered manufacturer’ means a  
6           manufacturer—

7           “(A) that is required to register under sec-  
8           tion 302(a)(1); and

9           “(B) manufactures a controlled substance  
10          in schedule II;

11          “(4) the term ‘covered officer’, with respect to  
12          a covered person means—

13          “(A) in the case of a covered person that  
14          is not an individual—

15                  “(i) the chief executive officer of the  
16                  covered person;

17                  “(ii) the president of the covered per-  
18                  son;

19                  “(iii) the chief medical officer of the  
20                  covered person; and

21                  “(iv) the chief counsel of the covered  
22                  person; and

23          “(B) in the case of a covered person that  
24          is an individual, that individual; and

1           “(5) the term ‘covered person’ means a covered  
2       dispenser, a covered distributor, or a covered manu-  
3       facturer.

4       “(b) CERTIFICATIONS RELATING TO DIVERSION  
5       CONTROLS.—Not later than 180 days after the date of  
6       enactment of this section, and each year thereafter, each  
7       covered officer of a covered person shall submit to the At-  
8       torney General, for each controlled substance in schedule  
9       II dispensed, distributed, or manufactured by the covered  
10      person, a certification—

11           “(1) signed by the covered officer; and

12           “(2) certifying that—

13               “(A) the covered person maintains effective  
14              controls against diversion of the controlled sub-  
15              stance into channels other than legitimate med-  
16              ical, scientific, research, or industrial channels;

17               “(B) all information contained in any  
18              record, inventory, or report required to be kept  
19              or submitted to the Attorney General by the  
20              covered person under section 307, or under any  
21              regulation issued under that section, is accu-  
22              rate; and

23               “(C) the covered person is in compliance  
24              with all applicable requirements under Federal

1 law relating to reporting suspicious orders for  
2 controlled substances.

3 “(c) CERTIFICATIONS RELATING TO MIS-  
4 BRANDING.—Not later than 180 days after the date of en-  
5 actment of this section, and each year thereafter, each cov-  
6 ered officer of a covered manufacturer shall submit to the  
7 Attorney General, for each controlled substance in sched-  
8 ule II manufactured by the covered manufacturer, a cer-  
9 tification—

10 “(1) signed by the covered officer; and

11 “(2) certifying that the controlled substance is  
12 not misbranded, as described in section 502 of the  
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
14 352).”.

15 (b) OFFENSES.—Part D of title II of the Controlled  
16 Substances Act (21 U.S.C. 841 et seq.) is amended by  
17 adding at the end the following:

18 “CERTIFICATIONS BY COVERED OFFICERS

19 “SEC. 424. (a) DEFINITIONS.—In this section, the  
20 terms ‘covered dispenser’, ‘covered distributor’, ‘covered  
21 manufacturer’, ‘covered officer’, and ‘covered person’ have  
22 the meanings given those terms in section 312.

23 “(b) OFFENSES.—

24 “(1) FAILURE TO SUBMIT CERTIFICATIONS.—

25 “(A) CERTIFICATIONS RELATING TO DI-  
26 VERSION CONTROLS.—It shall be unlawful for a

1 covered officer of a covered person to fail to  
2 submit a certification required under section  
3 312(b), without regard to the state of mind of  
4 the covered officer.

5 “(B) CERTIFICATIONS RELATING TO MIS-  
6 BRANDING.—It shall be unlawful for a covered  
7 officer of a covered manufacturer to fail to sub-  
8 mit a certification required under section  
9 312(c), without regard to the state of mind of  
10 the covered officer.

11 “(2) SUBMISSION OF FALSE CERTIFICATIONS.—

12 “(A) FALSE CERTIFICATIONS RELATING TO  
13 DIVERSION CONTROLS.—It shall be unlawful for  
14 a covered officer of a covered person to submit  
15 a certification required under section 312(b),  
16 without regard to the state of mind of the cov-  
17 ered officer, that contains a materially false  
18 statement or representation relating to the in-  
19 formation required to be certified under that  
20 section for the year for which the certification  
21 is submitted.

22 “(B) FALSE CERTIFICATIONS RELATING  
23 TO MISBRANDING.—It shall be unlawful for a  
24 covered officer of a covered manufacturer to  
25 submit a certification required under section

1           312(c), without regard to the state of mind of  
 2           the covered officer, that contains a materially  
 3           false statement or representation relating to the  
 4           misbranding of a controlled substance with re-  
 5           spect to the year for which the certification is  
 6           submitted.

7           “(c) PENALTIES.—

8                 “(1) CIVIL PENALTIES.—Except as provided in  
 9           paragraph (2), a covered officer who violates sub-  
 10          section (b) shall be subject to a civil penalty of not  
 11          more than \$25,000.

12                “(2) CRIMINAL PENALTIES.—A covered officer  
 13          who knowingly violates subsection (b)(2) shall be  
 14          subject to criminal penalties under section 403(d).

15          “(d) COMPREHENSIVE ADDICTION RESOURCES  
 16          FUND.—

17                “(1) ESTABLISHMENT.—There is established in  
 18          the Treasury a fund to be known as the ‘Com-  
 19          prehensive Addiction Resources Fund’.

20                “(2) TRANSFER OF AMOUNTS.—There shall be  
 21          transferred to the Comprehensive Addiction Re-  
 22          sources Fund 100 percent of—

23                         “(A) any civil penalty paid to the United  
 24          States under this section; and

1           “(B) any fine paid to the United States  
2           under section 403(d) for a knowing violation of  
3           subsection (b)(2) of this section.

4           “(3) AVAILABILITY AND USE OF FUNDS.—  
5           Amounts transferred to the Comprehensive Addic-  
6           tion Fund under paragraph (2) shall—

7                   “(A) remain available until expended; and

8                   “(B) be made available to supplement  
9           amounts appropriated to carry out title XXXIV  
10          of the Public Health Service Act.”.

11          (c) CRIMINAL PENALTIES.—Section 403 of the Con-  
12       trolled Substances Act (21 U.S.C. 843) is amended—

13               (1) in subsection (d)(1)—

14                   (A) by inserting “or knowingly violates sec-  
15           tion 424(b)(2)” after “any person who violates  
16           this section”; and

17                   (B) by striking “violation of this section”  
18           and inserting “such a violation”; and

19               (2) in subsection (f)—

20                   (A) in paragraph (1), by striking “or 416”  
21           and inserting “or section 416, or knowing viola-  
22           tions of section 424(b)(2)”; and

23                   (B) in paragraph (3), by inserting “or  
24           knowing violations of section 424(b)(2)” before  
25           the period at the end.

1 (d) TECHNICAL AND CONFORMING AMENDMENTS.—

2 The table of contents for the Comprehensive Drug Abuse  
3 Prevention and Control Act of 1970 (Public Law 91–513;  
4 84 Stat. 1236) is amended—

5 (1) by inserting after the item relating to sec-  
6 tion 311 the following:

“Sec. 312. Certifications relating to diversion controls and misbranding.”;

7 and

8 (2) by inserting after the item relating to sec-  
9 tion 423 the following:

“Sec. 424. Certifications by covered officers.”.

10 (e) EFFECTIVE DATE.—The amendments made by  
11 subsections (b) and (c) of this section shall take effect on  
12 the date that is 180 days after the date of enactment of  
13 this Act.

