

115TH CONGRESS  
2D SESSION

# H. R. 5545

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 HOUSE OF REPRESENTATIVES

APRIL 18, 2018

Mr. CUMMINGS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, and Natural Resources, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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,*

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

4 (a) **SHORT TITLE.**—This Act may be cited as the  
 5 “Comprehensive Addiction Resources Emergency Act of  
 6 2018”.

7 (b) **TABLE OF CONTENTS.**—The table of contents of  
 8 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:

1 **“TITLE XXXIV—SUBSTANCE USE**  
2 **AND OPIOID HEALTH RE-**  
3 **SOURCES**

4 **“Subtitle A—Substance Use and**  
5 **Opioid Emergency Relief Grant**  
6 **Program**

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

8 “(a) IN GENERAL.—The Secretary, in coordination  
9 with the Director of the Office of National Drug Control  
10 Policy, shall award grants to eligible localities for the pur-  
11 pose of addressing substance use within such localities.

12 “(b) ELIGIBILITY.—

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

15 “(A) be—

16 “(i) a county that can demonstrate  
17 that the rate of drug overdose deaths per  
18 100,000 individuals residing in the county  
19 during the most recent 3-year period for  
20 which such data are available was not less  
21 than the rate of such deaths for the county  
22 that ranked at the 67th percentile of all  
23 counties, as determined by the Secretary;

24 “(ii) a county that can demonstrate  
25 that the number of drug overdose deaths

1 during the most recent 3-year period for  
2 which such data are available was not less  
3 than the number of such deaths for the  
4 county that ranked at the 90th percentile  
5 of all counties, as determined by the Sec-  
6 retary; or

7 “(iii) a city that is located within a  
8 county described in clause (i) or (ii), that  
9 meets the requirements of paragraph (3);  
10 and

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

13 “(2) MULTIPLE CONTIGUOUS COUNTIES.—In  
14 the case of an eligible county that is contiguous to  
15 one or more other eligible counties within the same  
16 State, the group of counties shall—

17 “(A) be considered as a single eligible  
18 county for purposes of a grant under this sec-  
19 tion;

20 “(B) submit a single application under sec-  
21 tion 3404;

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

24 “(D) establish, through intergovernmental  
25 agreements, an administrative mechanism to al-

1 locate funds and substance use disorder treat-  
2 ment services under the grant based on—

3 “(i) the number and rate of drug  
4 overdose deaths and nonfatal drug  
5 overdoses in each of the counties that com-  
6 pose the eligible county;

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

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

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

13 “(A) IN GENERAL.—A city that is within  
14 an eligible county described in paragraph (1),  
15 or a group of counties that is within a group of  
16 counties determined to be an eligible county  
17 under paragraph (2), shall be eligible to receive  
18 a grant under section 3401 if such city or coun-  
19 ty or group of counties meets the requirements  
20 of subparagraph (B).

21 “(B) REQUIREMENTS.—A city or county  
22 meets the requirements of this subparagraph if  
23 such city or county—

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

4 “(ii) meets the requirements of para-  
5 graph (1)(A);

6 “(iii) submits an application under  
7 section 3404;

8 “(iv) establishes a planning council  
9 (for purposes of section 3402); and

10 “(v) establishes an administrative  
11 mechanism to allocate funds and services  
12 under the grant based on—

13 “(I) the number and rate of drug  
14 overdose deaths and nonfatal drug  
15 overdoses in the city or county;

16 “(II) the severity of need for sub-  
17 stance use disorder treatment services  
18 in the city or county; and

19 “(III) the health and support  
20 personnel needs of the city or county.

21 “(C) POPULATION EXCEPTION.—A city or  
22 county or group of counties that does not meet  
23 the requirements of subparagraph (B)(i) may  
24 apply to the Secretary for a waiver of such re-

1           requirement. Such application shall dem-  
2           onstrate—

3                   “(i) that the needs of the population  
4                   to be served are distinct or that addressing  
5                   substance use in the service area would be  
6                   best served by the formation of an inde-  
7                   pendent council; and

8                   “(ii) that the city or county or group  
9                   of counties has the capacity to administer  
10                  the funding received under this subtitle.

11                  “(D) MINIMUM FUNDING.—A city or coun-  
12                  ty that meets the requirement of this paragraph  
13                  and receives a grant under section 3401 shall  
14                  be entitled to an amount of funding under the  
15                  grant in an amount that is not less than the  
16                  amount determined under section 3403(a) with  
17                  respect to such city or county.

18                  “(4) INDEPENDENT CITY.—Independent cities  
19                  that are not located within the territory of a county  
20                  shall be treated as eligible counties for purposes of  
21                  this subtitle.

22                  “(5) POLITICAL SUBDIVISIONS.—With respect  
23                  to States that do not have a local county system of  
24                  governance, the Secretary shall determine the local  
25                  political subdivisions within such States that are eli-



1       gible to receive a grant under section 3401 and such  
2       subdivisions shall be treated as eligible counties for  
3       purposes of this subtitle.

4               “(6) DETERMINATIONS WHERE THERE IS A  
5       LACK OF DATA.—The Secretary shall establish eligi-  
6       bility and allocation criteria related to the prevalence  
7       of drug overdose deaths, the mortality rate from  
8       drug overdoses, and that provides an equivalent  
9       measure of need for funding for cities and counties  
10      for which the data described in paragraph (1)(A) or  
11      (2)(D)(i) is not available.

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

1 ing to provide assistance related to substance use  
2 and addiction.

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

5 “(A) a city or county described in para-  
6 graph (1);

7 “(B) multiple contiguous counties de-  
8 scribed in paragraph (2);

9 “(C) an independent locality described in  
10 paragraph (3);

11 “(D) an independent city described in  
12 paragraph (4); and

13 “(E) a political subdivision described in  
14 paragraph (5).

15 “(c) ADMINISTRATION.—

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

20 “(2) MULTIPLE CONTIGUOUS COUNTIES.—

21 “(A) IN GENERAL.—Except as provided in  
22 subparagraph (B), in the case of an eligible  
23 county described in subsection (b)(2), assist-  
24 ance made available under a grant awarded  
25 under this section shall be directed to the chief

1 elected official of the particular county des-  
2 ignated in the application submitted for the  
3 grant under section 3404. Such chief elected of-  
4 ficial shall be the administrator of the grant.

5 “(B) STATE ADMINISTRATION.—Notwith-  
6 standing subparagraph (A), the eligible county  
7 described in subsection (b)(2) may elect to des-  
8 ignate the chief elected State official of the  
9 State in which the eligible county is located as  
10 the administrator of the grant funds.

11 **“SEC. 3402. PLANNING COUNCIL.**

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

17 “(1) be representative of the demographics of  
18 the population of individuals with substance use dis-  
19 order in the area; and

20 “(2) include representatives of—

21 “(A) health care providers, including feder-  
22 ally qualified health centers, rural health clinics,  
23 Indian health programs as defined in section 4  
24 of the Indian Health Care Improvement Act,  
25 urban Indian organizations as defined in section

1 4 of the Indian Health Care Improvement Act,  
2 Native Hawaiian organizations as defined in  
3 section 12 of the Native Hawaiian Health Care  
4 Act of 1988, and facilities operated by the De-  
5 partment of Veterans Affairs;

6 “(B) community-based health, harm reduc-  
7 tion, or addiction service organizations, includ-  
8 ing, where applicable, representatives of Drug  
9 Free Communities Coalition grantees;

10 “(C) social service providers, including pro-  
11 viders of housing and homelessness services and  
12 recovery residence providers;

13 “(D) mental health care providers;

14 “(E) local public health agencies;

15 “(F) law enforcement officials, including  
16 officials from High Intensity Drug Trafficking  
17 Area program, where applicable;

18 “(G) affected communities, including indi-  
19 viduals with substance use disorder or a history  
20 of substance use disorder, including individuals  
21 in recovery from substance use disorders;

22 “(H) State governments, including the  
23 State Medicaid agency and the Single State  
24 Agency for Substance Abuse Services;

25 “(I) local governments;

1 “(J) non-elected community leaders;

2 “(K) substance use disorder treatment pro-  
3 viders;

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

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

9 “(N) historically underserved groups and  
10 subpopulations;

11 “(O) individuals who were formerly incar-  
12 cerated;

13 “(P) organizations serving individuals who  
14 are currently or were formerly incarcerated;

15 “(Q) representatives of Federal agencies;

16 “(R) representatives of organizations that  
17 provide services to youth at risk of substance  
18 use;

19 “(S) representatives of medical examiners  
20 or coroners;

21 “(T) representatives of labor unions and  
22 the workplace community; and

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

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

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

6           “(2) CONSIDERATION REGARDING DESIGNATION  
7 OF COUNCIL.—In making a determination of wheth-  
8 er to establish or designate a council under para-  
9 graph (1), the chief elected official shall give priority  
10 to the designation of an existing entity that has  
11 demonstrated experience in the provision of health  
12 and support services to individuals with substance  
13 use disorder within the eligible local area, that has  
14 a structure that recognizes the Federal trust respon-  
15 sibility when spending Federal health care dollars,  
16 and that has demonstrated a commitment to re-  
17 specting the obligation of government agencies using  
18 Federal dollars to consult with Indian tribes and  
19 confer with Urban Indian health programs.

20           “(3) JOINT COUNCIL.—The Secretary shall es-  
21 tablish a process to permit an eligible local area that  
22 is not contiguous with any other eligible local area  
23 to form a joint planning council with such other eli-  
24 gible local area or areas, as long as such areas are  
25 located in geographical proximity to each other, as

1 determined by the Secretary, and submit a joint ap-  
2 plication under section 3404.

3 “(4) JOINT COUNCIL ACROSS STATE LINES.—  
4 Eligible local areas may form a joint planning coun-  
5 cil with other eligible local areas across State lines  
6 if such areas are located in geographical proximity  
7 to each other, as determined by the Secretary, sub-  
8 mit a joint application under section 3404, and es-  
9 tablish intergovernmental agreements to allow the  
10 administration of the grant across State lines.

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

13 “(1) be nominated and selected through an  
14 open process;

15 “(2) elect from among their membership a chair  
16 and vice chair;

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

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

23 “(d) MEMBERSHIP TERMS.—Members of the plan-  
24 ning council established or designated under subsection

1 (a) may serve additional terms if nominated and selected  
2 through the process established in subsection (e)(1).

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

5 “(1) establish priorities for the allocation of  
6 grant funds within the eligible local area that em-  
7 phasize reducing drug overdose and substance use  
8 disorder through evidence-based interventions in  
9 both community and criminal justice settings and  
10 that are based on—

11 “(A) the use by the grantee of substance  
12 use disorder treatment and intervention strate-  
13 gies that comply with best practices identified  
14 by the Secretary;

15 “(B) the demonstrated or probable cost-ef-  
16 fectiveness of proposed substance use disorder  
17 treatment services;

18 “(C) the health priorities of the commu-  
19 nities within the eligible local area that are af-  
20 fected by substance use;

21 “(D) the priorities and needs of individuals  
22 with substance use disorder; and

23 “(E) the availability of other governmental  
24 and nongovernmental services;



1           “(2) ensure the use of grant funds are con-  
2           sistent with any existing State or local plan regard-  
3           ing the provision of substance use disorder treat-  
4           ment services to individuals with substance use dis-  
5           order;

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

10           “(4) regularly assess the efficiency of the ad-  
11           ministrative mechanism in rapidly allocating funds  
12           to support evidence-based substance use disorder  
13           treatment services in the areas of greatest need  
14           within the eligible local area;

15           “(5) work with local public health agencies to  
16           determine the size and demographics of the popu-  
17           lation of individuals with substance use disorders  
18           and the types of substance use that are most preva-  
19           lent in the eligible local area;

20           “(6) work with local public health agencies to  
21           determine the needs of such population, including  
22           the need for substance use disorder treatment serv-  
23           ices;

24           “(7) work with local public agencies to deter-  
25           mine the disparities in access to services among af-

1 affected subpopulations and historically underserved  
2 communities, including infrastructure and capacity  
3 shortcomings of providers that contribute to these  
4 disparities;

5 “(8) work with local public agencies to establish  
6 methods for obtaining input on community needs  
7 and priorities, including by partnering with organi-  
8 zations that serve targeted communities experiencing  
9 high opioid related health disparities to gather data  
10 using culturally attuned data collection methodolo-  
11 gies;

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

15 “(10) annually assess the effectiveness of the  
16 substance use disorder treatment services being sup-  
17 ported by the grant received by the eligible local  
18 area, including—

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

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

23 “(C) long-term outcomes among individ-  
24 uals receiving treatment for substance use dis-  
25 orders; and

1           “(D) the availability of substance use dis-  
2           order treatment services needed by individuals  
3           with substance use disorders over their life-  
4           times.

5           “(f) CONFLICTS OF INTEREST.—

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

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

22          “(g) GRIEVANCE PROCEDURES.—A planning council  
23          under subsection (a) shall develop procedures for address-  
24          ing grievances with respect to funding under this subtitle,  
25          including procedures for submitting grievances that can-

1 not be resolved to binding arbitration. Such procedures  
2 shall be described in the by-laws of the planning council.

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

6 “(1) The meetings of the council shall be open  
7 to the public and shall be held only after adequate  
8 notice to the public.

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

14 “(3) Detailed minutes of each meeting of the  
15 council shall be kept. The accuracy of all minutes  
16 shall be certified to by the chair of the council.

17 “(4) This subparagraph does not apply to any  
18 disclosure of information of a personal nature that  
19 would constitute a clearly unwarranted invasion of  
20 personal privacy, including any disclosure of medical  
21 information or personnel matters.

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

23 “(a) AMOUNT OF GRANT.—

24 “(1) GRANTS BASED ON RELATIVE NEED OF  
25 AREA.—

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

7           “(B) EXPEDITED DISTRIBUTION.—Not  
8 later than 90 days after an appropriation be-  
9 comes available to carry out this subtitle for a  
10 fiscal year, the Secretary shall disburse 53 per-  
11 cent of the amount made available under sec-  
12 tion 3406 for carrying out this subtitle for such  
13 fiscal year through grants to eligible local areas  
14 under section 3401, in accordance with sub-  
15 paragraphs (C) and (D).

16           “(C) AMOUNT.—

17           “(i) IN GENERAL.—Subject to the ex-  
18 tent of amounts made available in appro-  
19 priations Acts, a grant made for purposes  
20 of this subparagraph to an eligible local  
21 area shall be made in an amount equal to  
22 the product of—

23                   “(I) an amount equal to the  
24                   amount available for distribution

1 under subparagraph (B) for the fiscal  
2 year involved; and

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

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

10 “(ii) DISTRIBUTION FACTOR.—For  
11 purposes of clause (i)(II), the term ‘dis-  
12 tribution factor’ means—

13 “(I) an amount equal to—

14 “(aa) the estimated number  
15 of drug overdose deaths in the el-  
16 igible local area, as determined  
17 under clause (iii); or

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

22 as determined by the Secretary based  
23 on which distribution factor (item (aa)  
24 or (bb)) will result in the eligible local

1 area receiving the greatest amount of  
2 funds; or

3 “(II) in the case of an eligible  
4 local area for which the data de-  
5 scribed in subclause (I) is not avail-  
6 able, an amount determined by the  
7 Secretary—

8 “(aa) based on other data  
9 the Secretary determines appro-  
10 priate; and

11 “(bb) that is related to the  
12 prevalence of non-fatal drug  
13 overdoses, drug overdose deaths,  
14 and the mortality rate from drug  
15 overdoses and provides an equiv-  
16 alent measure of need for fund-  
17 ing.

18 “(iii) NUMBER OF DRUG OVERDOSE  
19 DEATHS.—The number of drug overdose  
20 deaths determined under this clause for an  
21 eligible county for a fiscal year for pur-  
22 poses of clause (ii) is the number of drug  
23 overdose deaths during the most recent 3-  
24 year period for which such data are avail-  
25 able.

1           “(iv) NUMBER OF NON-FATAL DRUG  
2           OVERDOSES.—The number of non-fatal  
3           drug overdose deaths determined under  
4           this clause for an eligible county for a fis-  
5           cal year for purposes of clause (ii) may be  
6           determined by using data including emer-  
7           gency department syndromic data, visits,  
8           or other emergency medical services for  
9           drug-related causes during the most recent  
10          3-year period for which such data are  
11          available.

12          “(v) STUDY.—Not later than 3 years  
13          after the date of enactment of this title,  
14          the Comptroller General shall conduct a  
15          study to determine whether the data uti-  
16          lized for purposes of clause (ii) provide the  
17          most precise measure of local area need re-  
18          lated to substance use and addiction preva-  
19          lence in local areas and whether additional  
20          data would provide more precise measures  
21          of substance use and addiction prevalence  
22          in local areas. Such study shall identify  
23          barriers to collecting or analyzing such  
24          data, and make recommendations for revis-  
25          ing the distribution factors used under



1           such clause to determine funding levels in  
2           order to direct funds to the local areas in  
3           most need of funding to provide substance  
4           use disorder treatment services.

5           “(vi) REDUCTIONS IN AMOUNTS.—If a  
6           local area that is an eligible local area for  
7           a year loses such eligibility in a subsequent  
8           year based on the failure to meet the re-  
9           quirements of section 3401(b)(1)(A), such  
10          area will remain eligible to receive—

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

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

19          “(2) SUPPLEMENTAL GRANTS.—

20                   “(A) IN GENERAL.—The Secretary shall  
21                   disburse the remainder of amounts not dis-  
22                   bursed under paragraph (1) for such fiscal year  
23                   for the purpose of making grants to cities and  
24                   counties whose application under section  
25                   3404—

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

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

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

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

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

21          “(vi) demonstrates the inclusiveness of  
22          affected communities and individuals with  
23          substance use disorders, including those  
24          communities and individuals that are dis-

1 proportionately affected or historically un-  
2 derserved;

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

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

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

18 “(B) AMOUNT.—

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

1           “(I) the rate of drug overdose  
2           deaths per 100,000 population in the  
3           eligible local area; and

4           “(II) the increasing need for sub-  
5           stance use disorder treatment serv-  
6           ices, including relative rates of in-  
7           crease in the number of drug  
8           overdoses or drug overdose deaths, re-  
9           cent increases in drug overdoses or  
10          drug overdose deaths since data was  
11          provided under section 3401(b), if ap-  
12          plicable.

13          “(ii) DEMONSTRATED NEED.—The  
14          factors considered by the Secretary in de-  
15          termining whether a local area has a dem-  
16          onstrated need for purposes of clause  
17          (i)(II) may include any or all of the fol-  
18          lowing:

19                 “(I) The unmet need for sub-  
20                 stance use disorder treatment serv-  
21                 ices, including factors identified in  
22                 subparagraph (B)(i)(II).

23                 “(II) Relative rates of increase in  
24                 the number of drug overdoses or drug  
25                 overdose deaths.

1           “(III) The relative rates of in-  
2           crease in the number of drug  
3           overdoses or drug overdose deaths  
4           within new or emerging subpopula-  
5           tions.

6           “(IV) The current prevalence of  
7           substance use disorders.

8           “(V) Relevant factors related to  
9           the cost and complexity of delivering  
10          substance use disorder treatment serv-  
11          ices to individuals in the eligible local  
12          area.

13          “(VI) The impact of co-morbid  
14          factors, including co-occurring condi-  
15          tions, determined relevant by the Sec-  
16          retary.

17          “(VII) The prevalence of home-  
18          lessness among individuals with sub-  
19          stance use disorders.

20          “(VIII) The relevant factors that  
21          limit access to health care, including  
22          geographic variation, adequacy of  
23          health insurance coverage, and lan-  
24          guage barriers.

1           “(IX) The impact of a decline in  
2           the amount received pursuant to para-  
3           graph (1) on substance use disorder  
4           treatment services available to all in-  
5           dividuals with substance use disorders  
6           identified and eligible under this sub-  
7           title.

8           “(X) The increasing incidence in  
9           conditions related to substance use,  
10          including hepatitis C, human immuno-  
11          deficiency virus, hepatitis B and other  
12          infections associated with injection  
13          drug use.

14          “(C) APPLICATION OF PROVISIONS.—A  
15          local area that receives a grant under this para-  
16          graph—

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

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

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

23          “(3) AMOUNT OF GRANT TO TRIBAL GOVERN-  
24          MENTS.—

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

5           “(B) FORMULA GRANTS.—The Secretary,  
6           acting through the Indian Health Service, shall  
7           use 10 percent of the amount available under  
8           section 3406 for each fiscal year to provide for-  
9           mula grants to Indian tribes disproportionately  
10          affected by substance use, in an amount deter-  
11          mined pursuant to a formula and eligibility cri-  
12          teria developed by the Secretary in consultation  
13          with Indian tribes, for the purposes of address-  
14          ing substance use.

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

22          “(b) USE OF AMOUNTS.—

23                 “(1) REQUIREMENTS.—The Secretary may not  
24                 make a grant under section 3401 to an eligible local

1 area unless the chief elected official of the area  
2 agrees that—

3 “(A) the allocation of funds and services  
4 within the area under the grant will be made in  
5 accordance with the priorities established by the  
6 substance use disorder treatment services plan-  
7 ning council; and

8 “(B) funds provided under this grant will  
9 be expended for—

10 “(i) prevention services described in  
11 paragraph (3);

12 “(ii) core medical services described in  
13 paragraph (4);

14 “(iii) recovery and support services  
15 described in paragraph (5);

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

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

20 “(vi) financial assistance with health  
21 insurance described in paragraph (8); and

22 “(vii) administrative expenses de-  
23 scribed in paragraph (10).

24 “(2) DIRECT FINANCIAL ASSISTANCE.—



1           “(A) IN GENERAL.—An eligible local area  
2 shall use amounts received under a grant under  
3 section 3401 to provide direct financial assist-  
4 ance to eligible entities for the purpose of pro-  
5 viding prevention services, core medical services,  
6 recovery and support services, harm reduction  
7 services, and early intervention and engagement  
8 services.

9           “(B) APPROPRIATE ENTITIES.—Direct fi-  
10 nancial assistance may be provided under sub-  
11 paragraph (A) to public or nonprofit private en-  
12 tities, or private for-profit entities if such enti-  
13 ties are the only available provider of quality  
14 substance use disorder treatment services in the  
15 area.

16           “(3) PREVENTION SERVICES.—

17           “(A) IN GENERAL.—For purposes of this  
18 subsection, the term ‘prevention services’ means  
19 services, programs, or multi-sector strategies to  
20 prevent substance use disorder (such as evi-  
21 dence-based education campaigns, community-  
22 based prevention programs, opioid diversion,  
23 collection and disposal of unused opioids, and  
24 services to at-risk populations).

1           “(B) LIMIT.—An eligible local area may  
2 use not to exceed 20 percent of the amount of  
3 the grant under section 3401 for prevention  
4 services. An eligible local area may apply to the  
5 Secretary for a waiver of this subparagraph.

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

11           “(A) Substance use disorder treatments,  
12 including clinical stabilization services, with-  
13 drawal management and detoxification, inten-  
14 sive inpatient treatment, intensive outpatient  
15 treatment, all forms of Federally-approved  
16 medication-assisted treatment, outpatient treat-  
17 ment, and residential recovery treatment.

18           “(B) Outpatient and ambulatory health  
19 services, including those administered by Feder-  
20 ally qualified health centers and rural health  
21 clinics.

22           “(C) Hospice services.

23           “(D) Mental health services.

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

1           “(F) Pharmaceutical assistance and diag-  
2           nostic testing related to the management of  
3           substance-use disorders a co-morbid conditions.

4           “(G) Home and community based health  
5           services.

6           “(H) Comprehensive Case Management,  
7           including substance use disorder treatment ad-  
8           herence services.

9           “(I) Health insurance enrollment and cost-  
10          sharing assistance in accordance with para-  
11          graph (8).

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

1 ices, and referrals for job training and career serv-  
2 ices, housing, legal services, and child care and fam-  
3 ily services.

4 “(6) EARLY INTERVENTION AND ENGAGEMENT  
5 SERVICES.—For purposes of this section, the term  
6 ‘early intervention and engagement services’ means  
7 services to provide rapid access to substance use dis-  
8 order treatment, counseling provided to individuals  
9 who have misused substances, who have experienced  
10 an overdose, or are at risk of developing substance  
11 use disorder, and the provision of referrals to facili-  
12 tate the access of such individuals to core medical  
13 services or recovery and support services. The enti-  
14 ties through which such services may be provided in-  
15 clude emergency rooms, fire departments and emer-  
16 gency medical services, detention facilities, homeless  
17 shelters, law enforcement agencies, health care  
18 points of entry specified by eligible local areas, Fed-  
19 erally qualified health centers, and rural health clin-  
20 ics.

21 “(7) HARM REDUCTION SERVICES.—For pur-  
22 poses of this section, the term ‘harm reduction serv-  
23 ices’ means evidence-based services provided to indi-  
24 viduals engaging in substance use that reduce the

1 risk of infectious disease transmission, overdose, or  
2 death, including by increasing access to health care.

3 “(8) AFFORDABLE HEALTH INSURANCE COV-  
4 ERAGE.—An eligible local area may use amounts  
5 provided under a grant awarded under section 3401  
6 to establish a program of financial assistance to as-  
7 sist eligible individuals with substance use disorder  
8 in—

9 “(A) enrolling in health insurance cov-  
10 erage; or

11 “(B) affording health care services, includ-  
12 ing assistance paying cost-sharing amounts, in-  
13 cluding premiums.

14 “(9) REQUIREMENT OF STATUS AS MEDICAID  
15 PROVIDER.—

16 “(A) PROVISION OF SERVICE.—Subject to  
17 paragraph (2), the Secretary may not make a  
18 grant under section 3401 for the provision of  
19 substance use disorder treatment services under  
20 this section in an eligible local area unless, in  
21 the case of any such service that is available  
22 pursuant to the State plan approved under title  
23 XIX of the Social Security Act for the State—

24 “(i) the political subdivision involved  
25 will provide the service directly, and the

1 political subdivision has entered into a par-  
2 ticipation agreement under the State plan  
3 and is qualified to receive payments under  
4 such plan; or

5 “(ii) the eligible local area involved  
6 will enter into an agreement with a public  
7 or nonprofit private entity under which the  
8 entity will provide the service, and the enti-  
9 ty has entered into such a participation  
10 agreement and is qualified to receive such  
11 payments.

12 “(B) WAIVER.—

13 “(i) IN GENERAL.—In the case of an  
14 entity making an agreement pursuant to  
15 subparagraph (A)(ii) regarding the provi-  
16 sion of substance use disorder treatment  
17 services, the requirement established in  
18 such subparagraph shall be waived by the  
19 substance use planning council for the area  
20 involved if the entity does not, in providing  
21 health care services, impose a charge or ac-  
22 cept reimbursement available from any  
23 third-party payor, including reimbursement  
24 under any insurance policy or under any  
25 Federal or State health benefits program.

1                   “(ii) DETERMINATION.—A determina-  
2                   tion by the substance use planning council  
3                   of whether an entity referred to in clause  
4                   (i) meets the criteria for a waiver under  
5                   such clause shall be made without regard  
6                   to whether the entity accepts voluntary do-  
7                   nations for the purpose of providing serv-  
8                   ices to the public.

9                   “(10) ADMINISTRATION AND PLANNING.—An  
10                  eligible local area shall not use in excess of 10 per-  
11                  cent of amounts received under a grant under sec-  
12                  tion 3401 for administration, accounting, reporting,  
13                  and program oversight functions, including the de-  
14                  velopment of systems to improve data collection and  
15                  data sharing.

16                  “(11) INCARCERATED INDIVIDUALS.—Amounts  
17                  received under a grant under section 3401 may be  
18                  used to provide substance use disorder treatment  
19                  services to currently incarcerated individuals.

20                  **“SEC. 3404. APPLICATION.**

21                  “(a) IN GENERAL.—To be eligible to receive a grant  
22                  under section 3401, an eligible local area shall prepare and  
23                  submit to the Secretary an application in such form, and  
24                  containing such information, as the Secretary shall re-  
25                  quire, including—

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 through such  
4 disbursements;

5           “(2) a demonstration of the extent of local need  
6 for the funds under the grant and a plan for pro-  
7 posed substance use disorder treatment services that  
8 is consistent with local needs, including a com-  
9 prehensive plan for the use of the grant funds devel-  
10 oped by the planning council established under sec-  
11 tion 3402, except that the planning council require-  
12 ment shall not apply with respect to areas receiving  
13 supplemental grant funds under section 3403(a)(2);

14           “(3) a demonstration that the area will use  
15 funds in a manner that provides substance use dis-  
16 order treatment services compliant with the evi-  
17 dence-based standards developed in accordance with  
18 section 3434, including all forms of Federally-ap-  
19 proved medication-assisted treatments;

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

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



1           “(6) a demonstration that resources provided  
2           under the grant will be allocated in accordance with  
3           the local demographic incidence of substance use, in-  
4           cluding allocations for services for children, youths,  
5           and women;

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

10           “(8) a demonstration that at least one rep-  
11           resentative from Indian tribes located within any eli-  
12           gible local area are included in the membership of a  
13           planning council;

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

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

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

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

6           “(2) that the political subdivisions within the el-  
7 igible local area will maintain the level of expendi-  
8 tures by such political subdivisions for substance  
9 use-related services at a level that is equal to the  
10 level of such expenditures by such political subdivi-  
11 sions for the preceding fiscal year;

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

17           “(4) that substance use disorder treatment  
18 services provided with assistance made available  
19 under the grant will be provided without regard—

20                   “(A) to the ability of the individual to pay  
21 for such services; and

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

24           “(5) that substance use disorder treatment  
25 services will be provided in a setting that is acces-

1 sible to low-income individuals with substance use  
2 disorder, and to individuals with substance use dis-  
3 order residing in rural areas;

4 “(6) that a program of outreach will be pro-  
5 vided to low-income individuals with substance use  
6 disorder to inform such individuals of substance use  
7 disorder treatment services, and to individuals with  
8 substance use disorder residing in rural areas; and

9 “(7) that funds received under a grant awarded  
10 under this subtitle will not be utilized to make pay-  
11 ments for any item or service to the extent that pay-  
12 ment has been made, or can reasonably be expected  
13 to be made, with respect to that item or service  
14 under any State compensation program, under an  
15 insurance policy, or under any Federal or State  
16 health benefits program (except for a program ad-  
17 ministered by, or providing the services of, the In-  
18 dian Health Service).

19 “(c) REQUIREMENTS REGARDING IMPOSITION OF  
20 CHARGES FOR SERVICES.—

21 “(1) IN GENERAL.—The Secretary may not  
22 make a grant under section 3401 to an eligible local  
23 area unless the eligible local area provides assur-  
24 ances that in the provision of substance use disorder

1 treatment services with assistance provided under  
2 the grant—

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

8 “(B) in the case of individuals with an in-  
9 come greater than 138 percent of the official  
10 poverty level, the provider will impose a charge  
11 on each such individual according to a schedule  
12 of charges made available to the public;

13 “(C) in the case of individuals with an in-  
14 come greater than 138 percent of the official  
15 poverty level but not exceeding 200 percent of  
16 such poverty level, the provider will not, for an  
17 calendar year, impose charges in an amount ex-  
18 ceeding 5 percent of the annual gross income of  
19 the individual;

20 “(D) in the case of individuals with an in-  
21 come greater than 200 percent of the official  
22 poverty level but not exceeding 300 percent of  
23 such poverty level, the provider will not, for any  
24 calendar year, impose charges in an amount ex-

1           ceeding 7 percent of the annual gross income of  
2           the individual involved;

3           “(E) in the case of individuals with an in-  
4           come greater than 300 percent of the official  
5           poverty level, the provider will not, for any cal-  
6           endar year, impose charges in an amount ex-  
7           ceeding 15 percent of the annual gross income  
8           of the individual involved; and

9           “(F) in the case of eligible American In-  
10          dian and Alaska Native individuals as defined  
11          by section 447.50 of title 42, Code of Federal  
12          Regulations (as in effect on July 1, 2010), the  
13          provider will not impose any charges for sub-  
14          stance use disorder treatment services, includ-  
15          ing any charges or cost-sharing prohibited by  
16          section 1402(d) of the Patient Protection and  
17          Affordable Care Act.

18          “(2) CHARGES.—With respect to compliance  
19          with the assurances made under paragraph (1), an  
20          eligible local area may, in the case of individuals  
21          subject to a charge—

22                 “(A) assess the amount of the charge in  
23                 the discretion of the area, including imposing  
24                 only a nominal charge for the provision of sub-  
25                 stance use disorder treatment services, subject

1 to the provisions of the paragraph regarding  
2 public schedules and regarding limitations on  
3 the maximum amount of charges; and

4 “(B) take into consideration the total med-  
5 ical expenses of individuals in assessing the  
6 amount of the charge, subject to such provi-  
7 sions.

8 “(3) AGGREGATE CHARGES.—The Secretary  
9 may not make a grant under section 3401 to an eli-  
10 gible local area unless the area agrees that the limi-  
11 tations on charges for substance use disorder treat-  
12 ment services under this subsection applies to the  
13 annual aggregate of charges imposed for such serv-  
14 ices, however the charges are characterized, includes  
15 enrollment fees, premiums, deductibles, cost sharing,  
16 co-payments, co-insurance costs, or any other  
17 charges.

18 “(d) INDIAN TRIBES.—Any application requirements  
19 for grants distributed in accordance with section  
20 3403(a)(3) shall be developed by the Secretary in con-  
21 sultation with Indian tribes.

22 **“SEC. 3405. TECHNICAL ASSISTANCE.**

23 “The Secretary shall, beginning on the date of enact-  
24 ment of this title, provide technical assistance, including  
25 assistance from other grantees, contractors or subcontract-

1 tors under this title to assist newly eligible local areas in  
2 the establishment of planning councils and, to assist enti-  
3 ties in complying with the requirements of this subtitle  
4 in order to make such areas eligible to receive a grant  
5 under this subtitle. The Secretary may make planning  
6 grants available to eligible local areas, in an amount not  
7 to exceed \$75,000 for any area, that is projected to be  
8 eligible for funding under section 3401 in the following  
9 fiscal year. Such grant amounts shall be deducted from  
10 the first year formula award to eligible local areas accept-  
11 ing such grants.

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

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

15 “(1) \$2,700,000,000 for fiscal year 2019;

16 “(2) \$2,700,000,000 for fiscal year 2020;

17 “(3) \$2,700,000,000 for fiscal year 2021;

18 “(4) \$2,700,000,000 for fiscal year 2022;

19 “(5) \$2,700,000,000 for fiscal year 2023;

20 “(6) \$2,700,000,000 for fiscal year 2024;

21 “(7) \$2,700,000,000 for fiscal year 2025;

22 “(8) \$2,700,000,000 for fiscal year 2026;

23 “(9) \$2,700,000,000 for fiscal year 2027; and

24 “(10) \$2,700,000,000 for fiscal year 2028.

1 **“Subtitle B—State and Tribal Sub-**  
2 **stance Use Disorder Prevention**  
3 **and Intervention Grant Pro-**  
4 **gram**

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

6 “The Secretary, acting in coordination with the Di-  
7 rector of the Office of National Drug Control Policy, shall  
8 award grants to States, territories, and tribal governments  
9 for the purpose of addressing substance use within such  
10 States.

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

12 “(a) AMOUNT OF GRANT TO STATES AND TERRI-  
13 TORIES.—

14 “(1) IN GENERAL.—

15 “(A) EXPEDITED DISTRIBUTION.—Not  
16 later than 90 days after an appropriation be-  
17 comes available, the Secretary shall disburse 50  
18 percent of the amount made available under  
19 section 3415 for carrying out this subtitle for  
20 such fiscal year through grants to States under  
21 section 3411, in accordance with subparagraphs  
22 (B) and (C).

23 “(B) MINIMUM ALLOTMENT.—Subject to  
24 the amount made available under section 3415,  
25 the amount of a grant under section 3411 for—



1           “(i) each of the 50 States, the District  
2 of Columbia, and Puerto Rico for a fiscal  
3 year shall be the greater of—

4                   “(I) \$2,000,000; or

5                   “(II) an amount determined  
6 under the subparagraph (C); and

7           “(ii) each territory other than Puerto  
8 Rico for a fiscal year shall be the greater  
9 of—

10                   “(I) \$500,000; or

11                   “(II) an amount determined  
12 under the subparagraph (C).

13           “(C) DETERMINATION.—

14                   “(i) FORMULA.—For purposes of sub-  
15 paragraph (B), the amount referred to in  
16 this subparagraph for a State (including a  
17 territory) for a fiscal year is—

18                   “(I) an amount equal to the  
19 amount made available under section  
20 3415 for the fiscal year involved for  
21 grants pursuant to subparagraph (B);  
22 and

23                   “(II) the percentage constituted  
24 by the sum of—

1           “(aa) the product of 0.85  
2           and the ratio of the State dis-  
3           tribution factor for the State or  
4           territory to the sum of the re-  
5           spective distribution factors for  
6           all States; and

7           “(bb) the product of 0.15  
8           and the ratio of the non-local dis-  
9           tribution factor for the State or  
10          territory (as determined under  
11          clause (iv)) to the sum of the re-  
12          spective non-local distribution  
13          factors for all States or terri-  
14          tories.

15           “(ii) STATE DISTRIBUTION FACTOR.—  
16          For purposes of clause (i)(II)(aa), the term  
17          ‘State distribution factor’ means an  
18          amount equal to—

19           “(I) the estimated number of  
20           drug overdose deaths in the State, as  
21           determined under clause (iii); or

22           “(II) the number of non-fatal  
23           drug overdoses in the State, as deter-  
24           mined under clause (iv);

1 as determined by the Secretary based on  
2 which distribution factor (subclause (I) or  
3 (II)) will result in the State receiving the  
4 greatest amount of funds.

5 “(iii) NUMBER OF DRUG  
6 OVERDOSES.—For purposes of clause (ii),  
7 the number of drug overdose deaths deter-  
8 mined under this clause for a State for a  
9 fiscal year is the number of drug overdose  
10 deaths during the most recent 3-year pe-  
11 riod for which such data are available.

12 “(iv) NUMBER OF NON-FATAL DRUG  
13 OVERDOSES.—For purposes of clause (ii),  
14 the number of non-fatal drug overdose  
15 deaths determined under this clause for  
16 State for a fiscal year for purposes of  
17 clause (ii) may be determined by using  
18 data including emergency department  
19 syndromic data, visits, or other emergency  
20 medical services for drug-related causes  
21 during the most recent 3-year period for  
22 which such data are available.

23 “(v) NON-LOCAL DISTRIBUTION FAC-  
24 TORS.—For purposes of clause (i)(II)(bb),

1 the term ‘non-local distribution factor’  
2 means an amount equal to the sum of—

3 “(I) the number of drug  
4 overdoses deaths in the State involved,  
5 as determined under clause (iii), or  
6 the number of non-fatal drug  
7 overdoses in the State, based on the  
8 criteria used by the State under  
9 clause (ii); less

10 “(II) the total number of drug  
11 overdose deaths or non-fatal drug  
12 overdoses that are within areas in  
13 such State or territory that are eligi-  
14 ble counties under section 3401.

15 “(vi) STUDY.—Not later than 3 years  
16 after the date of enactment of this title,  
17 the Comptroller General shall conduct a  
18 study to determine whether the data uti-  
19 lized for purposes of clause (ii) provides  
20 the most precise measure of State need re-  
21 lated to substance use and addiction preva-  
22 lence and whether additional data would  
23 provide more precise measures the levels of  
24 substance use and addiction prevalent in  
25 States. Such study shall identify barriers

1 to collecting or analyzing such data, and  
2 make recommendations for revising the  
3 distribution factors used under such clause  
4 to determine funding levels in order to di-  
5 rect funds to the States in most need of  
6 funding to provide substance use disorder  
7 treatment services.

8 “(2) SUPPLEMENTAL GRANTS.—

9 “(A) IN GENERAL.—Subject to subpara-  
10 graph (C), the Secretary shall disburse the re-  
11 mainder of amounts not disbursed under para-  
12 graph (1) for such fiscal year for the purpose  
13 of making grants to States whose application—

14 “(i) contains a report concerning the  
15 dissemination of emergency relief funds  
16 under paragraph (1) and the plan for utili-  
17 zation of such funds;

18 “(ii) demonstrates the need in such  
19 State, on an objective and quantified basis,  
20 for supplemental financial assistance to  
21 combat substance use disorder;

22 “(iii) demonstrates the existing com-  
23 mitment of local resources of the State,  
24 both financial and in-kind, to combating  
25 substance use disorder;

1           “(iv) demonstrates the ability of the  
2 State to utilize such supplemental financial  
3 resources in a manner that is immediately  
4 responsive and cost effective;

5           “(v) demonstrates that resources will  
6 be allocated in accordance with the local  
7 demographic incidence of substances use  
8 disorders and drug overdose mortality;

9           “(vi) demonstrates the inclusiveness of  
10 affected communities and individuals with  
11 substance use disorders, including those  
12 communities and individuals that are dis-  
13 proportionately affected or historically un-  
14 derserved;

15           “(vii) demonstrates the manner in  
16 which the proposed services are consistent  
17 with the local needs assessment and the  
18 statewide coordinated statement of need  
19 required under section 3413(e);

20           “(viii) demonstrates success in identi-  
21 fying individuals with substance use dis-  
22 orders; and

23           “(ix) demonstrates that support for  
24 substance use disorder treatment services  
25 is organized to maximize the value to the

1 population to be served with an appro-  
2 priate mix of substance use disorder treat-  
3 ment services and attention to transition in  
4 care.

5 “(B) AMOUNT.—

6 “(i) IN GENERAL.—The amount of  
7 each grant made for purposes of this para-  
8 graph shall be determined by the Sec-  
9 retary. In making such determination, the  
10 Secretary shall consider:

11 “(I) the rate of drug overdose  
12 deaths per 100,000 population in the  
13 State; and

14 “(II) the increasing need for sub-  
15 stance use disorder treatment serv-  
16 ices, including relative rates of in-  
17 crease in the number of drug  
18 overdoses or drug overdose deaths, or  
19 recent increases in drug overdoses or  
20 drug overdose deaths since the data  
21 was reported under section 3413.

22 “(ii) DEMONSTRATED NEED.—The  
23 factors considered by the Secretary in de-  
24 termining whether a State has a dem-  
25 onstrated need for purposes of subpara-

1 graph (A)(ii) may include any or all of the  
2 following:

3 “(I) The unmet need for such  
4 services, including the factors identi-  
5 fied in clause (i)(II).

6 “(II) Relative rates of increase in  
7 the number of drug overdoses or drug  
8 overdose deaths.

9 “(III) The relative rates of in-  
10 crease in the number of drug deaths  
11 within new or emerging subpopula-  
12 tions.

13 “(IV) The current prevalence of  
14 substance use disorders.

15 “(V) Relevant factors related to  
16 the cost and complexity of delivering  
17 substance use disorder treatment serv-  
18 ices to individuals in the State.

19 “(VI) The impact of co-morbid  
20 factors, including co-occurring condi-  
21 tions, determined relevant by the Sec-  
22 retary.

23 “(VII) The prevalence of home-  
24 lessness among individuals with sub-  
25 stance use disorder.



1           “(VIII) The relevant factors that  
2           limit access to health care, including  
3           geographic variation, adequacy of  
4           health insurance coverage, and lan-  
5           guage barriers.

6           “(IX) The impact of a decline in  
7           the amount received pursuant to para-  
8           graph (1) on substance use disorder  
9           treatment services available to all in-  
10          dividuals with substance use disorders  
11          identified and eligible under this sub-  
12          title.

13          “(X) The increasing incidence in  
14          conditions related to substance use,  
15          including hepatitis C, human immuno-  
16          deficiency virus, hepatitis B and other  
17          infections associated with injection  
18          drug use.

19          “(C) MODEL STANDARDS.—

20          “(i) PREFERENCE.—In determining  
21          whether a State will receive funds under  
22          this paragraph, except as provided in  
23          clause (ii), the Secretary shall give pref-  
24          erence to States that have adopted the

1 model standards developed in accordance  
2 with section 3434.

3 “(ii) REQUIREMENT.—Effective begin-  
4 ning in fiscal year 2025, the Secretary  
5 shall not award a grant under this para-  
6 graph to a State unless that State has  
7 adopted the model standards developed in  
8 accordance with section 3434.

9 “(3) AMOUNT OF GRANT TO TRIBAL GOVERN-  
10 MENTS.—

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

15 “(B) FORMULA GRANTS.—The Secretary,  
16 acting through the Indian Health Service, shall  
17 use 10 percent of the amount available under  
18 section 3415 for each fiscal year to provide for-  
19 mula grants to Indian tribes in an amount de-  
20 termined pursuant to a formula and eligibility  
21 criteria developed by the Secretary in consulta-  
22 tion with Indian tribes, for the purposes of ad-  
23 dressing substance use.

24 “(C) USE OF AMOUNTS.—Notwithstanding  
25 any requirements in this section, an Indian

1           tribe may use amounts provided under grants  
2           awarded under this paragraph for the uses  
3           identified in subsection (b) and any other activi-  
4           ties determined appropriate by the Secretary, in  
5           consultation with Indian tribes.

6           “(b) USE OF AMOUNTS.—

7                 “(1) IN GENERAL.—A State may use amounts  
8           provided under grants awarded under section 3411  
9           for—

10                     “(A) prevention services described in para-  
11                     graph (2);

12                     “(B) core medical services described in  
13                     paragraph (3);

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

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

18                     “(E) harm reduction services described in  
19                     paragraph (6); and

20                     “(F) administrative expenses described in  
21                     paragraph (8).

22           “(2) PREVENTION SERVICES.—

23                     “(A) IN GENERAL.—For purposes of this  
24                     subsection, the term ‘prevention services’ means  
25                     services, programs, or multi-sector strategies to

1 prevent substance use disorder (including evi-  
2 dence-based education campaigns, community-  
3 based prevention programs, opioid diversion,  
4 collection and disposal of unused opioids, and  
5 services to at-risk populations).

6 “(B) LIMIT.—A State may use not to ex-  
7 ceed 20 percent of the amount of the grant  
8 under section 3411 for prevention services. A  
9 State may apply to the Secretary for a waiver  
10 of this subparagraph.

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

16 “(A) Substance use disorder treatments,  
17 including clinical stabilization services, with-  
18 drawal management and detoxification, inten-  
19 sive inpatient treatment, intensive outpatient  
20 treatment, all forms of Federally-approved  
21 medication-assisted treatment, outpatient treat-  
22 ment, and residential recovery treatment.

23 “(B) Outpatient and ambulatory health  
24 services, including those administered by Feder-

1           ally qualified health centers and rural health  
2           clinics.

3           “(C) Hospice services.

4           “(D) Mental health services.

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

7           “(F) Pharmaceutical assistance related to  
8           the management of substance-use disorders and  
9           co-morbid conditions.

10          “(G) Home and community based health  
11          services.

12          “(H) Comprehensive Case Management  
13          and care coordination, including treatment ad-  
14          herence services.

15          “(I) Health insurance enrollment and cost-  
16          sharing assistance in accordance with sub-  
17          section (e).

18          “(4) RECOVERY AND SUPPORT SERVICES.—For  
19          purposes of paragraph (1)(C), the term ‘recovery  
20          and support services’ means services, subject to the  
21          approval of the Secretary, that are provided to indi-  
22          viduals with substance use disorder, including resi-  
23          dential recovery treatment and housing, including  
24          for individuals receiving medication-assisted treat-  
25          ment, long term recovery services, 24/7 hotline crisis

1 center services, medical transportation services, res-  
2 pite care for persons caring for individuals with sub-  
3 stance use disorder, child care and family services  
4 while an individual is receiving inpatient treatment  
5 services or at the time of outpatient services, out-  
6 reach services, peer recovery services, nutrition serv-  
7 ices, and referrals for job training and career serv-  
8 ices, housing, legal services, and child care and fam-  
9 ily services.

10 “(5) EARLY INTERVENTION AND ENGAGEMENT  
11 SERVICES.—For purposes of this subsection, the  
12 term ‘early intervention and engagement services’  
13 means services to provide rapid access to substance  
14 use disorder treatment services, counseling provided  
15 to individuals who have misused substances, who  
16 have experienced an overdose, or are at risk of devel-  
17 oping substance use disorder, and the provision of  
18 referrals to facilitate the access of such individuals  
19 to core medical services or recovery and support  
20 services. The entities through which such services  
21 may be provided include emergency rooms, fire de-  
22 partments and emergency medical services, detention  
23 facilities, homeless shelters, law enforcement agen-  
24 cies, health care points of entry specified by eligible

1 areas, Federally qualified health centers, and rural  
2 health clinics.

3 “(6) HARM REDUCTION SERVICES.—For pur-  
4 poses of this subsection, the term ‘harm reduction  
5 services’ means evidence-based services provided to  
6 individuals engaging in substance use disorder that  
7 reduce the risk of infectious disease transmission,  
8 overdose, or death, including by increasing access to  
9 health care.

10 “(7) AFFORDABLE HEALTH INSURANCE COV-  
11 ERAGE.—A State may use amounts provided under  
12 a grant awarded under section 3411 to establish a  
13 program of financial assistance to assist eligible indi-  
14 viduals with substance use disorder in—

15 “(A) enrolling in health insurance cov-  
16 erage; or

17 “(B) affording health care services, includ-  
18 ing assistance paying cost-sharing amounts, in-  
19 cluding premiums.

20 “(8) ADMINISTRATION AND PLANNING.—A  
21 State shall not use in excess of 10 percent of  
22 amounts received under a grant under section 3411  
23 for administration, accounting, reporting, and pro-  
24 gram oversight functions, including the development

1 of systems to improve data collection and data shar-  
2 ing.

3 “(9) INCARCERATED INDIVIDUALS.—Amounts  
4 received under a grant under section 3411 may be  
5 used to provide substance use disorder treatment  
6 services to currently incarcerated individuals.

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

8 “(a) APPLICATION.—To be eligible to receive a grant  
9 under section 3411, a State shall prepare and submit to  
10 the Secretary an application in such form, and containing  
11 such information, as the Secretary shall require, includ-  
12 ing—

13 “(1) a complete accounting of the disbursement  
14 of any prior grants received under this subtitle by  
15 the applicant and the results achieved by these ex-  
16 penditures;

17 “(2) a comprehensive plan for the use of the  
18 grant, including a demonstration of the extent of  
19 local need for the funds sought and a plan for pro-  
20 posed substance use disorder treatment services that  
21 is consistent with local needs;

22 “(3) a demonstration that the State will use  
23 funds in a manner that provides substance use dis-  
24 order treatment services compliant with the evi-  
25 dence-based standards developed in accordance with



1 section 3434, including all Federally-approved medi-  
2 cation-assisted treatments;

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

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

10 “(6) a demonstration that resources provided  
11 under the grant will be allocated in accordance with  
12 the local demographic incidence of substance use, in-  
13 cluding allocations for services for children, youths,  
14 and women;

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

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

22 “(9) an explanation of how income, asset, and  
23 medical expense criteria will be established and ap-  
24 plied to those who qualify for assistance under the  
25 program.

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

4               “(1) that funds received under the grant will be  
5 utilized to supplement not supplant other State or  
6 local funds made available in the year for which the  
7 grant is awarded to provide substance use disorder  
8 treatment services to individuals with substance use  
9 disorder;

10              “(2) that the political subdivisions within the  
11 State will maintain the level of expenditures by such  
12 political subdivisions for substance use disorder  
13 treatment services at a level that is equal to the level  
14 of such expenditures by such political subdivisions  
15 for the preceding fiscal year;

16              “(3) that political subdivisions within the State  
17 will not use funds received under a grant awarded  
18 under section 3411 in maintaining the level of sub-  
19 stance use disorder treatment services as required in  
20 paragraph (2);

21              “(4) that substance use disorder treatment  
22 services provided with assistance made available  
23 under the grant will be provided without regard—

24                      “(A) to the ability of the individual to pay  
25                      for such services; and

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

3           “(5) that substance use disorder treatment  
4           services will be provided in a setting that is acces-  
5           sible to low-income individuals with substance use  
6           disorders and to individuals with substance use dis-  
7           orders residing in rural areas;

8           “(6) that a program of outreach will be pro-  
9           vided to low-income individuals with substance use  
10          disorders to inform such individuals of substance use  
11          disorder treatment services and to individuals with  
12          substance use disorders residing in rural areas;

13          “(7) that Indian tribes are included in planning  
14          for the use of grant funds and that the Federal  
15          trust responsibility is upheld at all levels of program  
16          administration; and

17          “(8) that funds received under a grant awarded  
18          under this section will not be utilized to make pay-  
19          ments for any item or service to the extent that pay-  
20          ment has been made, or can reasonably be expected  
21          to be made, with respect to that item or service  
22          under a State compensation program, under an in-  
23          surance policy, or under any Federal or State health  
24          benefits program (except for a program administered

1 by or providing the services of the Indian Health  
2 Service).

3 “(c) MEDICAID IMD WAIVER APPLICATION RE-  
4 QUIREMENT.—A State shall not be eligible to receive a  
5 grant under this subtitle for a fiscal year unless the  
6 State—

7 “(1) has in effect for the year a waiver under  
8 section 1115 of the Social Security Act (42 U.S.C.  
9 1315) to provide medical assistance under the State  
10 plan under title XIX of such Act to individuals  
11 who—

12 “(A) have not attained age 65 (or, if the  
13 State provides the medical assistance described  
14 in section 1905(a)(16) of such Act, have at-  
15 tained age 21 but have not attained age 65);

16 “(B) are patients in an institution for  
17 mental diseases; and

18 “(C) are eligible for medical assistance  
19 under the State plan; or

20 “(2) has submitted an application for the year  
21 for such a waiver.

22 “(d) REQUIREMENTS REGARDING IMPOSITION OF  
23 CHARGES FOR SERVICES.—

24 “(1) IN GENERAL.—The Secretary may not  
25 make a grant under section 3411 to a State unless

1 the State provides assurances that in the provision  
2 of services with assistance provided under the  
3 grant—

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

9 “(B) in the case of individuals with an in-  
10 come greater than 138 percent of the official  
11 poverty level, the provider will impose a charge  
12 on each such individual according to a schedule  
13 of charges made available to the public;

14 “(C) in the case of individuals with an in-  
15 come greater than 138 percent of the official  
16 poverty level but not exceeding 200 percent of  
17 such poverty level, the provider will not, for an  
18 calendar year, impose charges in an amount ex-  
19 ceeding 5 percent of the annual gross income of  
20 the individual;

21 “(D) in the case of individuals with an in-  
22 come greater than 200 percent of the official  
23 poverty level but not exceeding 300 percent of  
24 such poverty level, the provider will not, for any  
25 calendar year, impose charges in an amount ex-

1           ceeding 7 percent of the annual gross income of  
2           the individual involved;

3           “(E) in the case of individuals with an in-  
4           come greater than 300 percent of the official  
5           poverty level, the provider will not, for any cal-  
6           endar year, impose charges in an amount ex-  
7           ceeding 15 percent of the annual gross income  
8           of the individual involved; and

9           “(F) in the case of eligible American In-  
10          dian and Alaska Native individuals as defined  
11          by section 447.50 of title 42, Code of Federal  
12          Regulations (as in effect on July 1, 2010), the  
13          provider will not impose any charges for sub-  
14          stance use disorder treatment services, includ-  
15          ing any charges or cost-sharing prohibited by  
16          section 1402(d) of the Patient Protection and  
17          Affordable Care Act.

18          “(2) CHARGES.—With respect to compliance  
19          with the assurances made under paragraph (1), a  
20          State may, in the case of individuals subject to a  
21          charge—

22                 “(A) assess the amount of the charge in  
23                 the discretion of the State, including imposing  
24                 only a nominal charge for the provision of serv-  
25                 ices, subject to the provisions of the paragraph

1           regarding public schedules and regarding limi-  
2           tations on the maximum amount of charges;  
3           and

4                   “(B) take into consideration the total med-  
5           ical expenses of individuals in assessing the  
6           amount of the charge, subject to such provi-  
7           sions.

8           “(3) AGGREGATE CHARGES.—The Secretary  
9           may not make a grant under section 3411 to a State  
10          unless the State agrees that the limitations on  
11          charges for substance use disorder treatment serv-  
12          ices under this subsection applies to the annual ag-  
13          gregate of charges imposed for such services, how-  
14          ever the charges are characterized, includes enroll-  
15          ment fees, premiums, deductibles, cost sharing, co-  
16          payments, co-insurance costs, or any other charges.

17          “(e) STATEWIDE COORDINATED STATEMENT OF  
18          NEED.—A State shall not be eligible to receive a grant  
19          under this subtitle for a fiscal year unless the State devel-  
20          ops and publishes a statewide coordinated statement of  
21          need, including a demonstration of the extent of State  
22          need for assistance in addressing addiction and substance  
23          use disorder in the State and identifying priorities for the  
24          delivery of essential services to individuals with substance  
25          use disorder and their families.

1       “(f) INDIAN TRIBES.—Any application requirements  
2 applying to grants distributed in accordance with section  
3 3412(c) shall be developed by the Secretary in consulta-  
4 tion with Indian tribes.

5       **“SEC. 3414. TECHNICAL ASSISTANCE.**

6       “The Secretary shall provide technical assistance in  
7 administering and coordinating the activities authorized  
8 under section 3412, including technical assistance for the  
9 development of State applications for supplementary  
10 grants authorized in section 3212(a)(2).

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

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

14               “(1) \$4,000,000,000 for fiscal year 2019;

15               “(2) \$4,000,000,000 for fiscal year 2020;

16               “(3) \$4,000,000,000 for fiscal year 2021;

17               “(4) \$4,000,000,000 for fiscal year 2022;

18               “(5) \$4,000,000,000 for fiscal year 2023;

19               “(6) \$4,000,000,000 for fiscal year 2024;

20               “(7) \$4,000,000,000 for fiscal year 2025;

21               “(8) \$4,000,000,000 for fiscal year 2026;

22               “(9) \$4,000,000,000 for fiscal year 2027; and

23               “(10) \$4,000,000,000 for fiscal year 2028.



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

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

3 “(a) IN GENERAL.—The Secretary shall award  
4 grants to public, nonprofit, and Native entities for the  
5 purpose of funding core medical services, recovery and  
6 support services, harm reduction services, administrative  
7 expenses, and early intervention and engagement services  
8 in accordance with this section.

9 “(b) ELIGIBILITY.—

10 “(1) ENTITIES.—Public, nonprofit, or Native  
11 entities eligible to receive a grant under subsection  
12 (a) may include—

13 “(A) federally qualified health centers  
14 under section 1905(l)(2)(B) of the Social Secu-  
15 rity Act;

16 “(B) family planning clinics;

17 “(C) rural health clinics;

18 “(D) Native entities, including Indian  
19 health programs as defined in section 4 of the  
20 Indian Health Care Improvement Act, urban  
21 Indian organizations as defined in section 4 of  
22 the Indian Health Care Improvement Act, and  
23 Native Hawaiian organizations as defined in  
24 section 12 of the Native Hawaiian Health Care  
25 Act of 1988;

1           “(E) community-based organizations, clin-  
2           ics, hospitals, and other health facilities that  
3           provide substance use disorder treatment serv-  
4           ices;

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

7           “(G) faith based organizations that provide  
8           substance use disorder treatment services.

9           “(2) UNDERSERVED POPULATIONS.—Entities  
10          described in paragraph (1) shall serve underserved  
11          populations which may include minority populations  
12          and Indian populations, ex-offenders, individuals  
13          with comorbidities including HIV/AIDS, hepatitis B  
14          or C, mental illness, or other behavioral health dis-  
15          orders, low-income populations, inner city popu-  
16          lations, and rural populations.

17          “(3) APPLICATION.—To be eligible to receive a  
18          grant under this section, a public or nonprofit entity  
19          described in this subsection shall prepare and submit  
20          to the Secretary an application in such form, and  
21          containing such information, as the Secretary shall  
22          require, including—

23                 “(A) a complete accounting of the dis-  
24                 bursement of any prior grants received under

1 this subtitle by the applicant and the results  
2 achieved by these expenditures;

3 “(B) a comprehensive plan for the use of  
4 the grant, including a demonstration of the ex-  
5 tent of local need for the funds sought and a  
6 plan for proposed substance use disorder treat-  
7 ment services that is consistent with local  
8 needs;

9 “(C) a demonstration that the grantee will  
10 use funds in a manner that provides substance  
11 use disorder treatment services compliant with  
12 the evidence-based standards developed in ac-  
13 cordance with section 3434, including all Feder-  
14 ally-approved medication-assisted treatments;

15 “(D) information on the number of individ-  
16 uals likely to be served by the funds sought, in-  
17 cluding demographic data on the populations to  
18 be served;

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

23 “(F) a demonstration that resources pro-  
24 vided under the grant will be allocated in ac-  
25 cordance with the local demographic incidence

1 of substance use, including allocations for serv-  
2 ices for children, youths, and women;

3 “(G) a demonstration that the confiden-  
4 tiality of individuals receiving substance use dis-  
5 order treatment services will be maintained in a  
6 manner not inconsistent with applicable law;  
7 and

8 “(H) an explanation of how income, asset,  
9 and medical expense criteria will be established  
10 and applied to those who qualify for assistance  
11 under the program.

12 “(c) REQUIREMENT OF STATUS AS MEDICAID PRO-  
13 VIDER.—

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

21 “(A) the political subdivision involved will  
22 provide the substance use disorder treatment  
23 service directly, and the political subdivision has  
24 entered into a participation agreement under

1 the State plan and is qualified to receive pay-  
2 ments under such plan; or

3 “(B) the political subdivision involved will  
4 enter into an agreement with a public or non-  
5 profit private entity under which the entity will  
6 provide the substance use disorder treatment  
7 service, and the entity has entered into such a  
8 participation agreement and is qualified to re-  
9 ceive such payments.

10 “(2) WAIVER.—

11 “(A) IN GENERAL.—In the case of an enti-  
12 ty making an agreement pursuant to paragraph  
13 (1)(B) regarding the provision of substance use  
14 disorder treatment services, the requirement es-  
15 tablished in such paragraph shall be waived by  
16 the State if the entity does not, in providing  
17 such services, impose a charge or accept reim-  
18 bursement available from any third-party payor,  
19 including reimbursement under any insurance  
20 policy or under any Federal or State health  
21 benefits program.

22 “(B) DETERMINATION.—A determination  
23 by the State of whether an entity referred to in  
24 subparagraph (A) meets the criteria for a waiv-  
25 er under such subparagraph shall be made

1 without regard to whether the entity accepts  
2 voluntary donations for the purpose of pro-  
3 viding services to the public.

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

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

9 “(2) FORMULA GRANTS.—The Secretary, acting  
10 through the Indian Health Service, shall use 10 per-  
11 cent of the amount available under section 3425 for  
12 each fiscal year to provide grants to Native entities  
13 in an amount determined pursuant to criteria devel-  
14 oped by the Secretary in consultation with Indian  
15 tribes, for the purposes of addressing substance use.

16 “(3) USE OF AMOUNTS.—Notwithstanding any  
17 requirements in this section, Native entities may use  
18 amounts provided under grants awarded under this  
19 section for the uses identified in section 3422 and  
20 any other activities determined appropriate by the  
21 Secretary, in consultation with Indian tribes.

22 **“SEC. 3422. USE OF AMOUNTS.**

23 “(a) USE OF FUNDS.—An entity shall use amounts  
24 received under a grant under section 3421 to provide di-

1 rect financial assistance to eligible entities for the purpose  
2 of delivering or enhancing—

3 “(1) prevention services described in subsection  
4 (b);

5 “(2) core medical services described in sub-  
6 section (c);

7 “(3) recovery and support services described in  
8 subsection (d);

9 “(4) early intervention and engagement services  
10 described in subsection (e);

11 “(5) harm reduction services described in sub-  
12 section (f); and

13 “(6) administrative expenses described in sub-  
14 section (g).

15 “(b) PREVENTION SERVICES.—For purposes of this  
16 subsection, the term ‘prevention services’ means services,  
17 programs, or multi-sector strategies to prevent substance  
18 use disorder, including evidence-based education cam-  
19 paigns, community-based prevention programs, opioid di-  
20 version, collection and disposal of unused opioids, and  
21 services to at-risk populations.

22 “(c) CORE MEDICAL SERVICES.—For purposes of  
23 this section, the term ‘core medical services’ means the  
24 following services when provided to individuals with sub-

1   stance use disorder or at risk for developing substance use  
2   disorder:

3           “(1) Substance use disorder treatments, includ-  
4           ing clinical stabilization services, withdrawal man-  
5           agement and detoxification, intensive inpatient treat-  
6           ment, intensive outpatient treatment, all forms of  
7           Federally-approved medication-assisted treatment,  
8           and residential recovery treatment.

9           “(2) Outpatient and ambulatory health services,  
10          including those administered by federally qualified  
11          health centers and rural health clinics.

12          “(3) Hospice services.

13          “(4) Mental health services.

14          “(5) Naloxone procurement, distribution, and  
15          training.

16          “(6) Pharmaceutical assistance and diagnostic  
17          testing related to the management of substance-use  
18          disorder and co-morbid conditions.

19          “(7) Home and community based health serv-  
20          ices.

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

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



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

16           “(e) EARLY INTERVENTION AND ENGAGEMENT  
17 SERVICES.—For purposes of this section, the term ‘early  
18 intervention and engagement services’ means services to  
19 provide rapid access to substance use disorder treatment  
20 services, counseling provided to individuals who have mis-  
21 used substances, who have experienced an overdose, or are  
22 at risk of developing substance use disorder and the provi-  
23 sion of referrals to facilitate the access of such individuals  
24 to core medical services or recovery and support services.  
25 The entities through which such services may be provided

1 include emergency rooms, fire departments and emergency  
2 medical services, detention facilities, homeless shelters,  
3 law enforcement agencies, health care points of entry spec-  
4 ified by eligible areas, Federally qualified health centers,  
5 and rural health clinics.

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

12 “(g) ADMINISTRATION AND PLANNING.—An entity  
13 shall not use in excess of 10 percent of amounts received  
14 under a grant under section 3421 for administration, ac-  
15 counting, reporting, and program oversight functions, in-  
16 cluding for the purposes of developing systems to improve  
17 data collection and data sharing.

18 **“SEC. 3423. TECHNICAL ASSISTANCE.**

19 “The Secretary may, directly or through grants or  
20 contracts, provide technical assistance to nonprofit private  
21 entities and Native entities regarding the process of sub-  
22 mitting to the Secretary applications for grants under sec-  
23 tion 3421, and may provide technical assistance with re-  
24 spect to the planning, development, and operation of any  
25 program or service carried out pursuant to such section.

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

2       “(a) IN GENERAL.—The Secretary may provide plan-  
3 ning grants to public, nonprofit private, and Native enti-  
4 ties for purposes of assisting such entities in expanding  
5 their capacity to provide substance use disorder treatment  
6 services in low-income communities and affected sub-  
7 populations that are underserved with respect to such  
8 services.

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

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

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

14               “(1) \$500,000,000 for fiscal year 2019;

15               “(2) \$500,000,000 for fiscal year 2020;

16               “(3) \$500,000,000 for fiscal year 2021;

17               “(4) \$500,000,000 for fiscal year 2022;

18               “(5) \$500,000,000 for fiscal year 2023;

19               “(6) \$500,000,000 for fiscal year 2024;

20               “(7) \$500,000,000 for fiscal year 2025;

21               “(8) \$500,000,000 for fiscal year 2026;

22               “(9) \$500,000,000 for fiscal year 2027; and

23               “(10) \$500,000,000 for fiscal year 2028.

1           **“Subtitle D—Miscellaneous**  
2                           **Provisions**

3   **“SEC. 3431. SPECIAL PROJECTS OF NATIONAL SIGNIFI-**  
4                           **CANCE.**

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

11          “(b) GRANTS.—The Secretary shall award grants  
12 under a project under subsection (a) to entities eligible  
13 for grants under subtitles A, B, and C based on newly  
14 emerging needs of individuals receiving assistance under  
15 this title.

16          “(c) REPLICATION.—The Secretary shall make infor-  
17 mation concerning successful models or programs devel-  
18 oped under this section available to grantees under this  
19 title for the purpose of coordination, replication, and inte-  
20 gration. To facilitate efforts under this subsection, the  
21 Secretary may provide for peer-based technical assistance  
22 for grantees funded under this section.

23          “(d) GRANTS TO TRIBAL GOVERNMENTS.—

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

1 section 4 of the Indian Self-Determination and Edu-  
2 cation Assistance Act.

3 “(2) USE OF FUNDS.—The Secretary, acting  
4 through the Indian Health Service, shall use 10 per-  
5 cent of the amount available under this section for  
6 each fiscal year to provide grants to Indian tribes  
7 for the purposes of supporting the development of  
8 innovative and original models for the delivery of  
9 substance use disorder treatment and services, in-  
10 cluding the development of culturally-informed care  
11 models.

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

14 “(1) \$500,000,000 for fiscal year 2019;

15 “(2) \$500,000,000 for fiscal year 2020;

16 “(3) \$500,000,000 for fiscal year 2021;

17 “(4) \$500,000,000 for fiscal year 2022;

18 “(5) \$500,000,000 for fiscal year 2023;

19 “(6) \$500,000,000 for fiscal year 2024;

20 “(7) \$500,000,000 for fiscal year 2025;

21 “(8) \$500,000,000 for fiscal year 2026;

22 “(9) \$500,000,000 for fiscal year 2027; and

23 “(10) \$500,000,000 for fiscal year 2028.

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

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

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

17           “(2) to train the faculty of schools of medicine,  
18 nursing, public health, osteopathic medicine, den-  
19 tistry, allied health, and mental health practice to  
20 teach health professions students to screen for and  
21 provide for the needs of individuals with substance  
22 use disorders or at risk of substance use; and

23           “(3) to develop and disseminate curricula and  
24 resource materials relating to evidence-based prac-  
25 tices for the screening, prevention, and treatment of  
26 substance use disorders, including information about

1       prescribing best practices, alternative pain therapies,  
2       and Federally-approved medication-assisted treat-  
3       ment options.

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

7               “(1) train, or result in the training of, health  
8       professionals, including counselors, case managers,  
9       social workers, peer recovery coaches, and harm re-  
10      duction workers, who will provide substance use dis-  
11      order treatments for underserved groups, including  
12      minority individuals and Indians with substance use  
13      disorder and other individuals who are at a high risk  
14      of substance use;

15              “(2) train, or result in the training of, minority  
16      health professionals and minority allied health pro-  
17      fessionals, including counselors, case managers, so-  
18      cial workers, peer recovery coaches, and harm reduc-  
19      tion workers, to provide substance use disorder  
20      treatment for individuals with such disease;

21              “(3) train or result in the training of individ-  
22      uals, including counselors, case managers, social  
23      workers, peer recovery coaches, and harm reduction  
24      workers, who will provide substance use disorder

1 treatment in rural or other areas that are under-  
2 served by current treatment structures; and

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

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

14 “(1) tribal colleges and universities;

15 “(2) Indian Health Service grant funded insti-  
16 tutions; and

17 “(3) Native partner institutions, including insti-  
18 tutions of higher education with medical training  
19 programs that partner with one or more Indian  
20 tribes, tribal organizations, Native Hawaiian organi-  
21 zations, or tribal colleges and universities to train  
22 Native health professionals that will provide sub-  
23 stance use disorder treatment services in Native  
24 communities.



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

3           “(1) \$400,000,000 for fiscal year 2019;

4           “(2) \$400,000,000 for fiscal year 2020;

5           “(3) \$400,000,000 for fiscal year 2021;

6           “(4) \$400,000,000 for fiscal year 2022;

7           “(5) \$400,000,000 for fiscal year 2023;

8           “(6) \$400,000,000 for fiscal year 2024;

9           “(7) \$400,000,000 for fiscal year 2025;

10          “(8) \$400,000,000 for fiscal year 2026;

11          “(9) \$400,000,000 for fiscal year 2027; and

12          “(10) \$400,000,000 for fiscal year 2028.

13   **“SEC. 3433. OTHER PROVISIONS.**

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

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

1           “(1) submits to the Secretary a justification  
2           containing such information as the Secretary shall  
3           require; and

4           “(2) agrees to require all entities offering sub-  
5           stance use disorder treatment services under the  
6           grant—

7                   “(A) to offer at least two Federally-ap-  
8                   proved forms of medication-assisted treatment  
9                   on site;

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

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

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

1 **“SEC. 3434. STANDARDS FOR SUBSTANCE USE DISORDER**  
2 **TREATMENT AND RECOVERY FACILITIES.**

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

8 “(b) CONTENTS.—The model standards promulgated  
9 under subsection (a) shall—

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

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

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

24 “(4) require that patients have access to li-  
25 censed substance use disorder treatment services, in-

1 including health care providers and physicians, for in-  
2 patient and outpatient care;

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

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

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

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

23 “(9) develop standards for licensed providers to  
24 ensure all patients receive an outpatient treatment  
25 and discharge plan;

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

8           “(A) application, inspection, and renewal  
9 procedures for recovery residences;

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

11           “(C) standards for equipping residences  
12 with naloxone and training residence owners,  
13 operators, and employees in the administration  
14 of naloxone;

15           “(D) standards for recovery residence own-  
16 ers and operators; and

17           “(E) standards to identify, disqualify from  
18 grant funding, and refer to the appropriate reg-  
19 ulatory authority any entity engaged in the so-  
20 liciting or receiving of a commission, benefit,  
21 bonus, rebate, kickback, or bribe, directly or in-  
22 directly, in cash or in kind, or engaging in any  
23 split-fee arrangement, aimed at inducing the re-  
24 ferral of a patient to or from a substance use  
25 disorder treatment service;

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

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

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

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

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

23          “(c) ANNUAL ASSESSMENT.—Beginning with respect  
24 to fiscal year 2021, the Secretary shall make a determina-  
25 tion with respect to each State on whether the State has

1 adopted the model standards promulgated in accordance  
2 with this section.

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

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

15       “(a) **ESTABLISHMENT OF PROGRAM.**—

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

1 delivery to States of the opioid overdose reversal  
2 drug products in accordance with this paragraph.

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

13 “(b) NEGOTIATION OF CONTRACTS WITH MANUFAC-  
14 TURERS.—

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



1       thority for which is not provided for in advance in  
2       appropriations Acts, for the purchase and delivery of  
3       opioid overdose reversal drug products under sub-  
4       section (a).

5           “(2) AUTHORITY TO DECLINE CONTRACTS.—  
6       The Secretary may decline to enter into contracts  
7       under this subsection and may modify or extend  
8       such contracts.

9           “(3) CONTRACT PRICE.—

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

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

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

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

11           “(B) a minimum of two doses packaged to-  
12 gether.

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

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

20           “(B) each State and Indian tribe, at the  
21 option of the State or tribe, shall be permitted  
22 to obtain additional quantities of opioid over-  
23 dose reversal drug products (subject to amounts  
24 specified to the Secretary by the State or tribe  
25 in advance of negotiations) through purchasing

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

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

18 “(6) CHARGES FOR SHIPPING AND HAN-  
19 DLING.—The Secretary may enter into a contract  
20 referred to in paragraph (1) only if the manufac-  
21 turer involved agrees to submit to the Secretary  
22 such reports as the Secretary determines to be ap-  
23 propriate to assure compliance with the contract and  
24 if, with respect to a State program under this sec-  
25 tion that does not provide for the direct delivery of

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

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

23 “(c) USE OF OPIOID OVERDOSE REVERSAL DRUG  
24 PRODUCT LIST.—Beginning not later than one year after  
25 the first contract has been entered into under this section,

1 the Secretary shall use, for the purpose of the purchase,  
2 delivery, and administration of opioid overdose reversal  
3 drug products under this section, the list established (and  
4 periodically reviewed and, as appropriate, revised) by an  
5 advisory committee, established by the Secretary and lo-  
6 cated within the Centers for Disease Control and Preven-  
7 tion, which considers the cost effectiveness of each opioid  
8 overdose reversal drug product.

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

13 “(1) First Responders, including—

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

16 “(B) all Tribal police departments;

17 “(C) all local fire departments, including  
18 career fire departments, combination fire de-  
19 partments, and volunteer fire departments; and

20 “(D) all local emergency medical services  
21 organizations, including volunteer emergency  
22 medical services organizations.

23 “(2) Public entities with authority to administer  
24 local public health services, including all local health

1 departments, for the purposes of making opioid over-  
2 dose reversal drug products available to—

3 “(A) public and nonprofit entities, includ-  
4 ing—

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

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

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

14 “(B) the general public.

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

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

22 “(2) beginning in the second year of the pro-  
23 gram, demonstrate a distribution rate of a minimum  
24 of 90 percent of the opioid overdose reversal drug  
25 products received under this program; and

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

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

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

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

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

24                 “(3) COMBINATION FIRE DEPARTMENT.—The  
25                 term ‘combination fire department’ means a fire de-

1 department that has paid firefighting personnel and  
2 volunteer firefighting personnel.

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

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



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

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

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

24          “(9) STANDING ORDER.—The term ‘standing  
25          order’ means a non-patient-specific order covering

1 administration of medication by others to a patient  
2 who may be unknown to the prescriber at the time  
3 of the order.

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

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

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

15 “(1) \$500,000,000 for fiscal year 2019;

16 “(2) \$500,000,000 for fiscal year 2020;

17 “(3) \$500,000,000 for fiscal year 2021;

18 “(4) \$500,000,000 for fiscal year 2022;

19 “(5) \$500,000,000 for fiscal year 2023;

20 “(6) \$500,000,000 for fiscal year 2024;

21 “(7) \$500,000,000 for fiscal year 2025;

22 “(8) \$500,000,000 for fiscal year 2026;

23 “(9) \$500,000,000 for fiscal year 2027; and

24 “(10) \$500,000,000 for fiscal year 2028.

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

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

9 “(1) \$1,000,000,000 for fiscal year 2019;

10 “(2) \$1,000,000,000 for fiscal year 2020;

11 “(3) \$1,000,000,000 for fiscal year 2021;

12 “(4) \$1,000,000,000 for fiscal year 2022;

13 “(5) \$1,000,000,000 for fiscal year 2023;

14 “(6) \$1,000,000,000 for fiscal year 2024;

15 “(7) \$1,000,000,000 for fiscal year 2025;

16 “(8) \$1,000,000,000 for fiscal year 2026;

17 “(9) \$1,000,000,000 for fiscal year 2027; and

18 “(10) \$1,000,000,000 for fiscal year 2028.

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

22 “(a) DATA COLLECTION.—The Centers for Disease  
23 Control and Prevention shall use a portion of the funding  
24 appropriated under this section to ensure that all States  
25 participate in the Enhanced State Opioid Overdose Sur-  
26 veillance program and to provide technical assistance to

1 medical examiners and coroners to facilitate improved  
2 data collection on fatal overdoses through such program.

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

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

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

20 “(1) \$400,000,000 for fiscal year 2019;

21 “(2) \$400,000,000 for fiscal year 2020;

22 “(3) \$400,000,000 for fiscal year 2021;

23 “(4) \$400,000,000 for fiscal year 2022;

24 “(5) \$400,000,000 for fiscal year 2023;

25 “(6) \$400,000,000 for fiscal year 2024;

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

5 **“SEC. 3438. DEFINITIONS.**

6           “In this title:

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

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

21           “(3) **STATE.**—

22           “(A) **IN GENERAL.**—The term ‘State’  
23           means each of the 50 States, the District of Co-  
24           lumbia, and each of the territories.

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

8           “(4) SUBSTANCE USE DISORDER TREAT-  
9       MENT.—

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

20           “(B) TYPES OF TREATMENT.—Substance  
21 use disorder treatments shall include the fol-  
22 lowing:

23           “(i) Clinical stabilization services,  
24 which are evidence-based services provided  
25 in secure, acute care facilities (which may

1 be referred to as ‘addictions receiving fa-  
2 cilities’) that, at a minimum—

3 “(I) provide detoxification and  
4 stabilization services;

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

7 “(III) that serve individuals  
8 found to be substance use impaired.

9 These can also be referred to as ‘Ad-  
10 dictions receiving facilities’.

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

18 “(iii) Intensive inpatient treatment,  
19 which is a service that provides a planned  
20 regimen of evidence-based evaluation, ob-  
21 servation, medical monitoring, and evi-  
22 dence-based rehabilitative services and  
23 interventions such as pharmacotherapy, be-  
24 havioral therapy, and counseling, 24 hours

1 per day, 7 days per week, in a highly  
2 structured, residential environment.

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

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

21 “(vi) Outpatient treatment, which is a  
22 service that provides a planned regimen of  
23 evidence-based evaluation, observation,  
24 medical monitoring, and evidence-based re-  
25 habilitative services and interventions such



1 as pharmacotherapy, behavioral therapy,  
2 and counseling in a structured, nonresiden-  
3 tial environment by appointment during  
4 scheduled operating hours.

5 “(vii) Residential recovery 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 provided  
12 in a structured, live-in environment within  
13 a nonhospital setting on a 24-hours-per-  
14 day, 7-days-per-week basis.

15 “(C) LIMITATION.—Substance use disorder  
16 treatment providers shall not include—

17 “(i) prevention only providers; and

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

22 “(5) SUBSTANCE USE DISORDER TREATMENT  
23 SERVICES.—The term ‘substance use disorder treat-  
24 ment services’ means any prevention services, core  
25 medical services, recovery and support services, early

1 intervention and engagement services, and harm re-  
2 duction services authorized under this title.”.

3 **SEC. 4. AMENDMENTS TO THE CONTROLLED SUBSTANCES**

4 **ACT.**

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

8 “CERTIFICATIONS RELATING TO DIVERSION CONTROLS  
9 AND MISBRANDING

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

11 “(1) the term ‘covered dispenser’—

12 “(A) means a dispenser—

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

15 “(ii) dispenses a controlled substance  
16 in schedule II; and

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

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

21 “(ii) operating in that capacity;

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

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

1           “(B) distributes a controlled substance in  
2           schedule II;

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

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

7           “(B) manufactures a controlled substance  
8           in schedule II;

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

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

13                 “(i) the chief executive officer of the  
14                 covered person;

15                 “(ii) the president of the covered per-  
16                 son;

17                 “(iii) the chief medical officer of the  
18                 covered person; and

19                 “(iv) the chief counsel of the covered  
20                 person; and

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

23          “(5) the term ‘covered person’ means a covered  
24          dispenser, a covered distributor, or a covered manu-  
25          facturer.

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

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

9               “(2) certifying that—

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

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

20                       “(C) the covered person is in compliance  
21 with all applicable requirements under Federal  
22 law relating to reporting suspicious orders for  
23 controlled substances.

24       “(c) CERTIFICATIONS RELATING TO MIS-  
25 BRANDING.—Not later than 180 days after the date of en-

1 actment of this section, and each year thereafter, each cov-  
2 ered officer of a covered manufacturer shall submit to the  
3 Attorney General, for each controlled substance in sched-  
4 ule II manufactured by the covered manufacturer, a cer-  
5 tification—

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

7 “(2) certifying that the controlled substance is  
8 not misbranded, as described in section 502 of the  
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
10 352).”.

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

14 “CERTIFICATIONS BY COVERED OFFICERS

15 “SEC. 424. (a) DEFINITIONS.—In this section, the  
16 terms ‘covered dispenser’, ‘covered distributor’, ‘covered  
17 manufacturer’, ‘covered officer’, and ‘covered person’ have  
18 the meanings given those terms in section 312.

19 “(b) OFFENSES.—

20 “(1) FAILURE TO SUBMIT CERTIFICATIONS.—

21 “(A) CERTIFICATIONS RELATING TO DI-  
22 VERSION CONTROLS.—It shall be unlawful for a  
23 covered officer of a covered person to fail to  
24 submit a certification required under section  
25 312(b), without regard to the state of mind of  
26 the covered officer.

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

7           “(2) SUBMISSION OF FALSE CERTIFICATIONS.—

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

18          “(B) FALSE CERTIFICATIONS RELATING  
19          TO MISBRANDING.—It shall be unlawful for a  
20          covered officer of a covered manufacturer to  
21          submit a certification required under section  
22          312(c), without regard to the state of mind of  
23          the covered officer, that contains a materially  
24          false statement or representation relating to the  
25          misbranding of a controlled substance with re-

1           spect to the year for which the certification is  
2           submitted.

3           “(c) PENALTIES.—

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

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

11          “(d) COMPREHENSIVE ADDICTION RESOURCES  
12          FUND.—

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

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

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

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

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

4                   “(A) remain available until expended; and

5                   “(B) be made available to supplement  
6           amounts appropriated to carry out title XXXIV  
7           of the Public Health Service Act.”.

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

10                   (1) in subsection (d)(1)—

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

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

16                   (2) in subsection (f)—

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

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

23           (d) TECHNICAL AND CONFORMING AMENDMENTS.—

24           The table of contents for the Comprehensive Drug Abuse



1 Prevention and Control Act of 1970 (Public Law 91–513;  
2 84 Stat. 1236) is amended—

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

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

5 and

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

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

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

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