

114TH CONGRESS
2D SESSION

S. 3075

To establish programs related to prevention of prescription opioid misuse,
and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 16, 2016

Mr. DURBIN introduced the following bill; which was read twice and referred
to the Committee on Finance

A BILL

To establish programs related to prevention of prescription
opioid misuse, and for other purposes.

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.**

4 This Act may be cited as the “Addiction Prevention
5 and Responsible Opioid Practices Act”.

6 **SEC. 2. OPIOID ACTION PLAN.**

7 (a) ADVISORY COMMITTEE.—

8 (1) NEW DRUG APPLICATION.—Except as pro-
9 vided in paragraph (4), prior to the approval of a
10 new drug that is an opioid under section 505 of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355), the Commissioner of Food and Drugs shall
3 refer such drug to an advisory committee of the
4 Food and Drug Administration to seek recommenda-
5 tions from such Committee.

6 (2) PEDIATRIC OPIOID LABELING.—The Com-
7 missioner of Food and Drugs shall convene the Pedi-
8 atric Advisory Committee of the Food and Drug Ad-
9 ministration to seek recommendations from such
10 Committee regarding a framework for the inclusion
11 of information in the labeling of drugs that are
12 opioids relating to the use of such drugs in pediatric
13 populations before such Commissioner approves any
14 labeling changes for drugs that are opioids intended
15 for use in pediatric populations.

16 (3) PUBLIC HEALTH EXEMPTION.—If the Com-
17 missioner of Food and Drugs finds that referring a
18 new opioid drug or drugs to an advisory committee
19 of the Food and Drug Administration as required
20 under paragraph (1) is not in the interest of pro-
21 tecting and promoting public health, and has sub-
22 mitted a notice containing the rationale for such a
23 finding to the Committee on Health, Education,
24 Labor, and Pensions of the Senate and the Com-
25 mittee on Energy and Commerce of the House of

1 Representatives, or if the matter that would be con-
2 sidered by such advisory committee with respect to
3 any such drug or drugs concerns bioequivalence,
4 sameness of active ingredient, or other criteria appli-
5 cable to applications submitted under section 505(j)
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 355(j)), the Commissioner shall not be re-
8 quired to refer such drug or drugs to an advisory
9 committee as required under paragraph (1).

10 (4) SUNSET.—Unless Congress reauthorizes
11 paragraphs (1) and (2), the requirements of such
12 paragraphs shall cease to be effective on October 1,
13 2022.

14 (b) EDUCATION FOR PRESCRIBERS OF OPIOIDS.—
15 Not later than 1 year after the date of enactment of this
16 Act, the Secretary of Health and Human Services, acting
17 through the Commissioner of Food and Drugs, as part
18 of the Food and Drug Administration’s evaluation of the
19 Extended-Release/Long-Acting Opioid Analgesics Risk
20 Evaluation and Mitigation Strategy, and in consultation
21 with the Director of the Centers for Disease Control and
22 Prevention, the Director of the National Institutes of
23 Health, the Administrator of the Agency for Healthcare
24 Research and Quality, the Administrator of the Drug En-
25 forcement Administration, and relevant stakeholders, shall

1 develop recommendations regarding education programs
2 for prescribers of opioids required to be disseminated
3 under section 505–1 of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355–1), including recommendations
5 for which prescribers should participate in such programs
6 and how often participation in such programs is necessary.

7 (c) GUIDANCE.—Not later than 1 year after the date
8 of enactment of this Act, the Commissioner of Food and
9 Drugs shall issue guidance on if and how the approved
10 labeling of a drug that is an opioid and is the subject of
11 an application under section 505(j) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 355(j)) may include
13 statements that such drug deters abuse.

14 **SEC. 3. OPIOID INFORMATIONAL DOCUMENTS.**

15 (a) IN GENERAL.—Subchapter A of chapter V of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
17 et seq.) is amended by inserting after section 505–1 the
18 following:

19 **“SEC. 505–2. OPIOID INFORMATIONAL DOCUMENTS.**

20 “(a) DEVELOPMENT OF MATERIALS.—The Commis-
21 sioner shall develop informational documents describing to
22 consumers of opioid drugs the risk factors for opioid-re-
23 lated harm, and shall submit such documents to the Direc-
24 tor of the Centers for Disease Control and Prevention for
25 approval.

1 “(b) LABELING REQUIREMENT.—The manufacturer
2 of any opioid drug approved under section 505 shall en-
3 sure that the appropriate informational documents devel-
4 oped under subsection (a), and approved by the Director
5 of the Centers for Disease Control and Prevention, are in-
6 cluded in the labeling of such drug.”.

7 (b) ENFORCEMENT.—Section 502 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
9 ed by adding at the end the following:

10 “(dd) If it is an opioid drug and the labeling does
11 not include the informational documents required under
12 section 505–2.”.

13 **SEC. 4. STRENGTHENING CONSIDERATIONS FOR DEA NAR-**
14 **COTIC QUOTAS.**

15 Section 306 of the Controlled Substances Act (21
16 U.S.C. 826) is amended by adding at the end the fol-
17 lowing:

18 “(i)(1) In fixing manufacturing quotas under this
19 section the Attorney General shall take into consideration
20 the impact of the manufacturing quotas on diversion and
21 efforts to reduce the costs, injuries, and deaths associated
22 with the abuse of prescription opioids and heroin in the
23 United States.

24 “(2)(A) Not later than 1 year after the date of enact-
25 ment of this subsection and every year thereafter, the At-

1 torney General shall publish the approved manufacturing
2 quota for each manufacturer of fentanyl, oxycodone,
3 hydromorphone, oxycodone, oxycodone, and hydromorphone for that
4 year.

5 “(B) For any year in which the approved manufac-
6 turing quota for a manufacturer for any substance de-
7 scribed in subparagraph (A) is higher than the approved
8 manufacturing quota for a manufacturer for the substance
9 in the previous year, the Attorney General shall publish
10 a report explaining why the public health benefits of in-
11 creasing such quota outweigh the consequences of having
12 an increased volume of such substance available for sale,
13 and potential diversion, in the United States.

14 “(C) For any substance described in subparagraph
15 (A) that is approved under section 505 of the Federal
16 Food, Drug, and Cosmetic Act after the date of enactment
17 of this subsection, the Attorney General shall publish a
18 report explaining what factors were taken into consider-
19 ation in setting the manufacturing quota for the sub-
20 stance.

21 “(3) Not later than 90 days after the date of enact-
22 ment of this subsection, the Attorney General shall submit
23 to Congress a report on—

24 “(A) how the Attorney General will ensure that
25 the process of fixing manufacturing quotas under

1 this section takes into consideration efforts to reduce
 2 the costs, injuries, and deaths associated with the
 3 abuse of prescription opioids and heroin;

4 “(B) formal steps that will be taken to improve
 5 data collection from approved drug collection recep-
 6 tacles, mail-back programs, and take-back events on
 7 the volume and class of controlled substances that
 8 are collected; and

9 “(C) how the information described in subpara-
 10 graphs (A) and (B) will influence the quota-setting
 11 process of the Attorney General in the following
 12 year.”.

13 **SEC. 5. CONTINUING MEDICAL EDUCATION AND PRESCRIP-**
 14 **TION DRUG MONITORING PROGRAM REG-**
 15 **ISTRATION FOR PRESCRIBERS.**

16 Section 303 of the Controlled Substances Act (21
 17 U.S.C. 823) is amended by adding at the end the fol-
 18 lowing:

19 “(k)(1) The Attorney General shall not register, or
 20 renew the registration of, a practitioner under subsection
 21 (f) who is licensed under State law to prescribe controlled
 22 substances in schedule II, III, or IV, unless the practi-
 23 tioner submits to the Attorney General, for each such reg-
 24 istration or renewal request, a written certification that—

1 “(A)(i) the practitioner has, during the 1-year
2 period preceding the registration or renewal request,
3 completed a training program described in para-
4 graph (2); or

5 “(ii) the practitioner, during the applicable reg-
6 istration period, will not prescribe such controlled
7 substances in amounts in excess of a 72-hour supply
8 (for which no refill is available); and

9 “(B) the practitioner has registered with the
10 prescription drug monitoring program of the State
11 in which the practitioner practices, if the State has
12 such program.

13 “(2) A training program described in this paragraph
14 is a training program that—

15 “(A) follows the best practices for pain manage-
16 ment, as described in the ‘Guideline for Prescribing
17 Opioids for Chronic Pain’ as published by the Cen-
18 ters for Disease Control and Prevention in 2016, or
19 any successor thereto;

20 “(B) includes information on—

21 “(i) recommending non-opioid and non-
22 pharmacological therapy;

23 “(ii) establishing treatment goals and eval-
24 uating patient risks;

1 “(iii) prescribing the lowest dose and few-
2 est number of pills considered effective;

3 “(iv) addictive and overdose risks of
4 opioids;

5 “(v) diagnosing and managing substance
6 use disorders, including linking patients to evi-
7 dence-based treatment;

8 “(vi) identifying narcotics-seeking behav-
9 iors; and

10 “(vii) using prescription drug monitoring
11 programs; and

12 “(C) is approved by the Secretary of Health
13 and Human Services.”.

14 **SEC. 6. REPORT ON PRESCRIBER EDUCATION COURSES**
15 **FOR MEDICAL AND DENTAL STUDENTS.**

16 Each school of medicine, school of osteopathic medi-
17 cine, and school of dentistry participating in a program
18 under title IV of the Higher Education Act of 1965 (20
19 U.S.C. 1070a et seq.), as a condition for such participa-
20 tion, shall submit an annual report to Congress on any
21 prescriber education courses focused specifically on pain
22 management and responsible opioid prescribing practices
23 that such school requires students to take, and whether
24 such courses are consistent with the most recently pub-
25 lished version of the “Guideline for Prescribing Opioids

1 for Chronic Pain” of the Centers for Disease Control and
2 Prevention.

3 **SEC. 7. REQUIREMENTS UNDER PRESCRIPTION DRUG MON-**
4 **ITORING PROGRAMS.**

5 (a) IN GENERAL.—Beginning 1 year after the date
6 of enactment of this Act, each State that receives funding
7 under the Harold Rogers Prescription Drug Monitoring
8 Program established under the Departments of Com-
9 merce, Justice, and State, the Judiciary, and Related
10 Agencies Appropriations Act, 2002 (Public Law 107–77;
11 115 Stat. 748), the controlled substance monitoring pro-
12 gram under section 3990 of the Public Health Service Act
13 (42 U.S.C. 280g–3), or the Prescription Drug Overdose:
14 Prevention for States program of the Centers for Disease
15 Control and Prevention shall—

16 (1) require practitioners, or their designees, in
17 the State to consult the database of the prescription
18 drug monitoring program before writing prescrip-
19 tions for controlled substances (as such term is de-
20 fined in section 102 of the Controlled Substances
21 Act (21 U.S.C. 802)) in schedule II, III, or IV
22 under section 202 of such Act (21 U.S.C. 812);

23 (2) require dispensers of controlled substances
24 in schedule II, III, or IV, or their designees, to input
25 data into the database of the prescription drug mon-

1 itoring program within 24 hours of filling a quali-
2 fying prescription, as required by the Attorney Gen-
3 eral and the Secretary of Health and Human Serv-
4 ices, including patient identifier information, the na-
5 tional drug code of the dispensed drug, date of dis-
6 pensing the drug, quantity and dosage of the drug
7 dispensed, form of payment, Drug Enforcement Ad-
8 ministration registration number of the practitioner,
9 Drug Enforcement Administration registration num-
10 ber of the dispenser;

11 (3) allow practitioners and dispensers to des-
12 ignate other appropriate individuals to act as agents
13 of such practitioners and dispensers for purposes of
14 obtaining and inputing data from the database for
15 purposes of complying with paragraphs (1) and (2),
16 as applicable;

17 (4) provide informational materials for practi-
18 tioners and dispensers to identify and refer patients
19 with possible substance use disorders to professional
20 treatment specialists;

21 (5) establish formal data sharing agreements to
22 foster electronic connectivity with the prescription
23 drug monitoring programs of each State (if such
24 State has such a program) with which the State
25 shares a border, to facilitate the exchange of infor-

1 mation through an established technology architec-
2 ture that ensures common data standards, privacy
3 protection, and secure and streamlined information
4 sharing;

5 (6) notwithstanding section 399O(f)(1)(B) of
6 the Public Health Service Act (42 U.S.C. 280g-
7 3(f)(1)(B)), authorize direct access to the State's
8 database of the prescription drug monitoring pro-
9 gram to all State law enforcement agencies, State
10 boards responsible for the licensure, regulation, or
11 discipline of practitioners, pharmacists, or other per-
12 sons authorized to prescribe, administer, or dispense
13 controlled substances; and

14 (7) in order to enhance accountability in pre-
15 scribing and dispensing patterns, not fewer than 4
16 times per year, proactively provide informational re-
17 ports on aggregate trends and individual outliers,
18 based on information available through the State
19 prescription drug monitoring program to—

20 (A) the State entities and persons de-
21 scribed in paragraph (6); and

22 (B) the Medicaid agency, workers com-
23 pensation programs, and the department of
24 public health of the State.

1 (b) TRANSPARENCY IN PRESCRIBING PRACTICES AND
2 INTERVENTION FOR HIGH PRESCRIBERS.—

3 (1) STATE REPORTING REQUIREMENT.—Each
4 State that receives funding under the Harold Rogers
5 Prescription Drug Monitoring Program established
6 under the Departments of Commerce, Justice, and
7 State, the Judiciary, and Related Agencies Approp-
8 riations Act, 2002 (Public Law 107–77; 115 Stat.
9 748), the controlled substance monitoring program
10 under section 3990 of the Public Health Service Act
11 (42 U.S.C. 280g–3), or the Prescription Drug Over-
12 dose: Prevention for States program of the Centers
13 for Disease Control and Prevention shall, twice per
14 year, submit to the Secretary of Health and Human
15 Services and the Administrator of the Drug Enforce-
16 ment Administration—

17 (A) a list of all practitioners and dis-
18 pensers who, in the applicable reporting period,
19 have prescribed or dispensed schedule II, III, or
20 IV opioids in the State;

21 (B) the amount of schedule II, III, or IV
22 opioids that were prescribed and dispensed by
23 each individual practitioner and dispenser de-
24 scribed in subparagraph (A); and

1 (C) any additional information that the
2 Secretary and Administrator may require to
3 support surveillance and evaluation of trends in
4 prescribing or dispensing of schedule II, III, or
5 IV opioids, or to identify possible non-medical
6 use and diversion of such substances.

7 (2) ANNUAL REPORT.—Not later than 1 year
8 after the date of enactment of this Act, and annually
9 thereafter, the Secretary of Health and Human
10 Services, in consultation with the Administrator of
11 the Drug Enforcement Administration, the Secretary
12 of Defense, the Secretary of Veterans Affairs, and
13 the Director of the Indian Health Service, shall sub-
14 mit to Congress, and make public, a report identi-
15 fying the geographic areas with the highest rates of
16 opioid prescribing in the Nation, by zip code.

17 (3) DEVELOPMENT OF ACTION PLAN.—

18 (A) INITIAL PLAN.—Not later than 1 year
19 after the date of enactment of this Act, the Sec-
20 retary of Health and Human Services, in con-
21 sultation with the Administrator of the Drug
22 Enforcement Administration, the Secretary of
23 Defense, the Secretary of Veterans Affairs, and
24 the Director of the Indian Health Service, shall
25 submit to Congress a plan of action, including

1 warning letters and enforcement mechanisms,
2 for addressing outliers in opioid prescribing
3 practices and ensuring an adequate Federal re-
4 sponse to protect the public health.

5 (B) UPDATED PLAN.—The Secretary of
6 Health and Human Services shall submit to
7 Congress updates to the plan of action de-
8 scribed in subparagraph (A), as such Secretary,
9 in consultation with the heads of agencies de-
10 scribed in such subparagraph, determines ap-
11 propriate.

12 (c) DEFINITIONS.—In this section, the terms “dis-
13 penser” and “practitioner” have the meanings given such
14 terms in section 102 of the Controlled Substances Act (21
15 U.S.C. 802).

16 (d) AUTHORIZATION OF APPROPRIATIONS.—In addi-
17 tion to any other amounts appropriated to carry out the
18 Prescription Drug Overdose: Prevention for States pro-
19 gram of the Centers for Disease Control and Prevention,
20 for purposes of enhancing the utilization, interoperability,
21 and integration of State prescription drug monitoring pro-
22 grams, there are authorized to be appropriated
23 \$70,000,000 for each of fiscal years 2017 through 2021.

1 **SEC. 8. DEVELOPMENT OF NEW PAIN-RELATED MEASURES**
2 **UNDER THE MEDICARE HOSPITAL VALUE-**
3 **BASED PURCHASING PROGRAM TO ELIMI-**
4 **NATE FINANCIAL INCENTIVES TO OVER-PRE-**
5 **SCRIBE OPIOIDS.**

6 Section 1886(o)(2)(B) of the Social Security Act (42
7 U.S.C. 1395ww(o)(2)(B)) is amended—

8 (1) in clause (i)(II), by inserting “, subject to
9 clause (iii),” after “shall”; and

10 (2) by adding at the end the following new
11 clause:

12 “(iii) DEVELOPMENT OF NEW PAIN-
13 RELATED MEASURES.—

14 “(I) MORATORIUM UNTIL NEW
15 MEASURES APPLICABLE.—For value-
16 based incentive payments made with
17 respect to discharges occurring during
18 fiscal year 2018 and each subsequent
19 fiscal year (before the first fiscal year
20 in which new measures are applicable
21 under subclause (II)(cc)), the Sec-
22 retary shall ensure that measures se-
23 lected under subparagraph (A) (such
24 as measures related to the Hospital
25 Consumer Assessment of Healthcare
26 Providers and Systems survey) do not

1 include measures based on any assess-
2 ments by patients, with respect to
3 hospital stays of such patients, of—

4 “(aa) the need of such pa-
5 tients, during such stay, for med-
6 icine for pain;

7 “(bb) how often, during
8 such stay, the pain of such pa-
9 tients was well controlled; or

10 “(cc) how often, during such
11 stay, the staff of the hospital in
12 which such stay occurred did ev-
13 erything they could to help the
14 patient with the pain experienced
15 by the patient.

16 “(II) DEVELOPMENT OF NEW
17 MEASURES.—

18 “(aa) DEVELOPMENT.—Not
19 later than 3 years after the date
20 of enactment of this clause, the
21 Secretary shall develop measures
22 of patient experience of care with
23 respect to pain management that
24 balance the breadth of effective
25 pain management tools with

1 awareness for the role of over-
2 prescribing (including, if appro-
3 priate, opioid-seeking behaviors)
4 in the prescription opioid epi-
5 demic.

6 “(bb) CONSULTATION.—The
7 Secretary shall consult with rel-
8 evant stakeholders in developing
9 measures under item (aa).

10 “(cc) APPLICATION FOR
11 VALUE-BASED INCENTIVE PAY-
12 MENTS.—For value-based incen-
13 tive payments made with respect
14 to discharges occurring during a
15 fiscal year beginning on or after
16 the date on which the Secretary
17 develops new measures under
18 item (aa), the Secretary shall en-
19 sure that measures selected
20 under subparagraph (A) (such as
21 measures related to the Hospital
22 Consumer Assessment of Health-
23 care Providers and Systems sur-
24 vey) include such new meas-
25 ures.”.

1 **SEC. 9. NATIONAL ACADEMY OF MEDICINE STUDY.**

2 (a) STUDY.—The Secretary of Health and Human
3 Services shall enter into a contract with the National
4 Academy of Medicine to carry out a study on the addition
5 of coverage under the Medicare program under title XVIII
6 of the Social Security Act of alternative treatment modalities
7 (such as integrative medicine, including acupuncture
8 and exercise therapy, neural stimulation, biofeedback, radiofrequency ablation, and trigger point injections) furnished to Medicare beneficiaries who suffer from acute or
10 chronic lower back pain. Such study shall, pursuant to the
11 contract under this paragraph, include an analysis of—

12 (1) scientific research on the short-term and
13 long-term impact of the addition of such coverage on
14 clinical efficacy for pain management of such beneficiaries;
15

16 (2) whether the lack of Medicare coverage for
17 alternative treatment modalities impacts the volume
18 of opioids prescribed for beneficiaries; and
19

20 (3) the cost to the Medicare program of the addition of such coverage to treat pain and mitigate the progression of chronic pain, as weighed against
21 the cost of opioid use disorder, overdose, readmission, subsequent surgeries, and utilization and expenditures under parts B and D of such title.
22
23
24
25

1 (b) REPORT.—Not later than 1 year after the date
 2 of enactment of this Act, pursuant to the contract under
 3 subsection (a), the National Academy of Medicine shall
 4 submit to Congress a report on the study under subsection
 5 (a).

6 (c) AUTHORIZATION OF APPROPRIATIONS.—To carry
 7 out this section, there are authorized to be appropriated
 8 such sums as may be necessary.

9 **SEC. 10. EXCISE TAX ON OPIOID PAIN RELIEVERS.**

10 (a) IN GENERAL.—Subchapter E of chapter 32 of the
 11 Internal Revenue Code of 1986 is amended by adding at
 12 the end the following new section:

13 **“SEC. 4192. OPIOID PAIN RELIEVERS.**

14 “(a) IN GENERAL.—There is hereby imposed on the
 15 manufacturer or producer of any taxable active opioid a
 16 tax equal to the amount determined under subsection (b).

17 “(b) AMOUNT DETERMINED.—The amount deter-
 18 mined under this subsection with respect to a manufac-
 19 turer or producer for a calendar year is 1 cent per milli-
 20 gram of taxable active opioid in the production or manu-
 21 facturing quota determined for such manufacturer or pro-
 22 ducer for the calendar year under section 306 of the Con-
 23 trolled Substances Act (21 U.S.C. 826).

24 “(c) TAXABLE ACTIVE OPIOID.—For purposes of this
 25 section—

1 “(1) IN GENERAL.—The term ‘taxable active
2 opioid’ means any controlled substance (as defined
3 in section 102 of the Controlled Substances Act (21
4 U.S.C. 802), as in effect on the date of the enact-
5 ment of this section) manufactured in the United
6 States which is opium, an opiate, or any derivative
7 thereof.

8 “(2) EXCLUSIONS.—

9 “(A) OTHER INGREDIENTS.—In the case
10 of a product that includes a taxable active
11 opioid and another ingredient, subsection (a)
12 shall apply only to the portion of such product
13 that is a taxable active opioid.

14 “(B) DRUGS USED IN ADDICTION TREAT-
15 MENT.—The term ‘taxable active opioid’ shall
16 not include any controlled substance (as so de-
17 fined) which is used exclusively for the treat-
18 ment of opioid addiction as part of a medica-
19 tion-assisted treatment.”.

20 (b) CLERICAL AMENDMENTS.—

21 (1) The heading of subchapter E of chapter 32
22 of the Internal Revenue Code of 1986 is amended by
23 striking “**Medical Devices**” and inserting
24 “**Other Medical Products**”.

1 (2) The table of subchapters for chapter 32 of
 2 such Code is amended by striking the item relating
 3 to subchapter E and inserting the following new
 4 item:

 “SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

5 (3) The table of sections for subchapter E of
 6 chapter 32 of such Code is amended by adding at
 7 the end the following new item:

 “Sec. 4192. Opioid pain relievers.”.

8 (c) EFFECTIVE DATE.—The amendments made by
 9 this section shall apply to calendar years beginning after
 10 the date of the enactment of this Act.

11 **SEC. 11. OPIOID CONSUMER ABUSE REDUCTION PROGRAM.**

12 (a) OPIOID TAKE-BACK PROGRAM.—Section 302 of
 13 the Controlled Substances Act (21 U.S.C. 822) is amend-
 14 ed by adding at the end the following:

15 “(h)(1) The Attorney General shall establish a na-
 16 tional take-back program for the safe and environmentally
 17 responsible disposal of controlled substances.

18 “(2) In establishing the take-back program required
 19 under paragraph (1), the Attorney General—

20 “(A) shall consult with the Secretary and the
 21 Administrator of the Environmental Protection
 22 Agency; and

23 “(B) may coordinate with States, law enforce-
 24 ment agencies, water resource management agencies,

1 manufacturers, practitioners, pharmacists, public
2 health entities, transportation and incineration serv-
3 ice contractors, and other entities and individuals, as
4 appropriate.

5 “(3) The take-back program established under para-
6 graph (1)—

7 “(A) shall—

8 “(i) ensure appropriate geographic dis-
9 tribution so as to provide—

10 “(I) reasonably convenient and equi-
11 table access to permanent take-back loca-
12 tions, including not less than 1 disposal
13 site for every 25,000 residents and not less
14 than 1 physical disposal site per town, city,
15 county, or other unit of local government,
16 where possible; and

17 “(II) periodic collection events and
18 mail-back programs, including public no-
19 tice of such events and programs, as a sup-
20 plement to the permanent take-back loca-
21 tions described in subclause (I), particu-
22 larly in areas in which the provision of ac-
23 cess to such locations at the level described
24 in that subclause is not possible;

1 “(ii) establish a process for the accurate
2 cataloguing and reporting of the quantities of
3 controlled substances collected; and

4 “(iii) include a public awareness campaign
5 and education of practitioners and pharmacists;
6 and

7 “(B) may work in coordination with State and
8 locally implemented public and private take-back
9 programs.

10 “(4) From time to time, beginning in the second cal-
11 endar year that begins after the date of enactment of this
12 subsection, the Secretary of the Treasury shall transfer
13 from the general fund of the Treasury an amount equal
14 to one-half of the total amount of taxes collected under
15 section 4192 of the Internal Revenue Code of 1986 to the
16 Attorney General to carry out this subsection. Amounts
17 transferred under this subparagraph shall remain avail-
18 able until expended.”.

19 (b) FUNDING OF SUBSTANCE ABUSE PROGRAMS.—
20 From time to time, beginning in the second calendar year
21 that begins after the date of enactment of this Act, the
22 Secretary of the Treasury shall transfer from the general
23 fund of the Treasury an amount equal to one-half of the
24 total amount of taxes collected under section 4192 of the
25 Internal Revenue Code of 1986, as added by this Act, to

1 the Director of the Center for Substance Abuse Treatment
2 of the Substance Abuse and Mental Health Services Ad-
3 ministration for programs of the Center, including the
4 Block Grants for Prevention and Treatment of Substance
5 Abuse program under subpart II of part B of title XIX
6 of the Public Health Service Act (42 U.S.C. 300x-21 et
7 seq.) and Programs of Regional and National Significance.
8 Amounts transferred under this subsection shall remain
9 available until expended.

10 **SEC. 12. GAO STUDY.**

11 Not later than 1 year after the date of enactment
12 of this Act, the Comptroller General of the United States
13 shall conduct a study evaluating the various State laws,
14 commercial insurance methods, and existing research on
15 requirements that place limitations on opioid prescribing
16 practices and provide analysis on best practices to address
17 over-prescribing of opioids, while ensuring that individuals
18 who need such opioids can access them safely. Such study
19 shall provide recommendations, including with respect
20 to—

- 21 (1) limiting first-time opioid prescriptions to a
22 patient for acute pain to a 72-hour supply;
- 23 (2) allowing patients or practitioners to request
24 that a prescription for a schedule II opioid be par-
25 tially filled by a pharmacist; and

1 (3) pain management treatment contracts be-
2 tween practitioners and patients that establish in-
3 formed consent regarding the expectations, risks,
4 long-term effects, and benefits of the course of
5 opioid treatment, treatment goals, the potential for
6 opioid misuse, abuse, or diversion, and requirements
7 and responsibilities of patients, such as submitting
8 to a urine drug screening.

○