

112TH CONGRESS  
1ST SESSION

# S. 507

To provide for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

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IN THE SENATE OF THE UNITED STATES

MARCH 8, 2011

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

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## A BILL

To provide for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

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 “Prescription Drug  
5 Abuse Prevention and Treatment Act of 2011”.

6       **SEC. 2. FINDINGS.**

7       Congress makes the following findings:

8               (1) Nonmedical use of prescription pain reliev-  
9       ers is a matter of increasing public health concern.

10       According to the Substance Abuse and Mental

1 Health Services Administration, the proportion of all  
2 substance abuse treatment admissions aged 12 or  
3 older that reported any pain reliever abuse increased  
4 more than 400 percent between 1998 and 2008,  
5 from 2.2 to 9.8 percent.

6 (2) In 2008, among the population of the  
7 United States aged 12 or older, nonmedical use of  
8 prescription pain relievers was the second most prev-  
9 alent type of illicit drug use, after marijuana use.

10 (3) When used properly under medical super-  
11 vision, prescription opiates enable individuals with  
12 chronic pain to lead productive lives. However, when  
13 taken without a physician's oversight and direction,  
14 opiates can cause serious adverse health effects, re-  
15 sulting in dependence, abuse, and death.

16 (4) As with any controlled substance, there is a  
17 risk of abuse of methadone and other opiates.

18 (5) Methadone is an extensively tested, federally  
19 approved, and widely accepted method of treating  
20 addiction to prescription pain relievers or opiates.

21 (6) For more than 30 years, this synthetic pre-  
22 scription drug has been used for pain management  
23 and treatment for addiction to heroin, morphine,  
24 and other opioid drugs.

1           (7) The efficacy and lower cost of methadone  
2           has resulted in its being prescribed for pain manage-  
3           ment.

4           (8) Prescriptions for methadone have increased  
5           by nearly 700 percent from 1998 through 2006.

6           (9) According to the Centers for Disease Con-  
7           trol and Prevention, the number of poisoning deaths  
8           involving methadone increased nearly 7-fold from al-  
9           most 790 in 1999 to almost 5,420 in 2006, which  
10          is the most rapid increase among opioid analgesics  
11          and other narcotics involved in poisoning deaths.

12          (10) The age-specific rates of methadone death  
13          are higher for persons age 35 to 44 and 45 to 54  
14          than for other age groups. However, the rate of  
15          methadone deaths in younger individuals (age 15 to  
16          24) increased 11-fold from 1999 through 2005.

17          (11) Deaths from methadone and other opiates  
18          may actually be underreported. There is no com-  
19          prehensive database of drug-related deaths in the  
20          United States.

21          (12) The lack of standardized reporting by  
22          Medical Examiners precludes a uniform definition of  
23          “cause of death” on death certificates.

24          (13) The Controlled Substances Act (21 U.S.C.  
25          801 et seq.) requires that every person who dis-

1       penses or who proposes to dispense controlled nar-  
2       cotics, including methadone, whether for pain man-  
3       agement or opioid treatment obtain a registration  
4       from Drug Enforcement Administration. Unfortu-  
5       nately there is no requirement as a condition of re-  
6       ceiving the registration that these practitioners re-  
7       ceive any education on the use of these controlled  
8       narcotics, including methadone.

9               (14) Current Federal oversight of methadone  
10       and other opioids is inadequate to address the grow-  
11       ing number of opioid-related overdoses and deaths.

12               (15) Federal legislation is needed to avert  
13       opioid abuse, misuse, and death, without reducing  
14       patient access to needed care.

15       **SEC. 3. CONSUMER EDUCATION CAMPAIGN.**

16       Part A of title V of the Public Health Service Act  
17       (42 U.S.C. 290aa et seq.) is amended by adding at the  
18       end the following:

19       **“SEC. 506C. CONSUMER EDUCATION CAMPAIGN.**

20               “(a) IN GENERAL.—The Administrator shall award  
21       grants to States and nonprofit entities for the purpose of  
22       conducting culturally sensitive consumer education about  
23       opioid abuse, including methadone abuse. Such education  
24       shall include information on the dangers of opioid abuse,  
25       how to prevent opioid abuse including through safe dis-

1 posal of prescription medications and other safety pre-  
2 cautions, and detection of early warning signs of addic-  
3 tion.

4 “(b) ELIGIBILITY.—To be eligible to receive a grant  
5 under subsection (a), an entity shall—

6 “(1) be a State or nonprofit entity; and

7 “(2) submit to the Administrator an application  
8 at such time, in such manner, and containing such  
9 information as the Administrator may require.

10 “(c) PRIORITY.—In awarding grants under this sec-  
11 tion, the Administrator shall give priority to applicants  
12 that are States or communities with a high incidence of  
13 abuse of methadone and other opioids, and opioid-related  
14 deaths.

15 “(d) EVALUATIONS.—The Administrator shall de-  
16 velop a process to evaluate the effectiveness of activities  
17 carried out by grantees under this section at reducing  
18 abuse of methadone and other opioids.

19 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
20 is authorized to be appropriated to carry out this section  
21 \$15,000,000 for each of fiscal years 2012 through 2016.”.

22 **SEC. 4. PRACTITIONER EDUCATION.**

23 (a) EDUCATION REQUIREMENTS.—

24 (1) REGISTRATION CONSIDERATION.—Section  
25 303(f) of the Controlled Substances Act (21 U.S.C.

1 823(f)) is amended by inserting after paragraph (5)  
2 the following:

3 “(6) The applicant’s compliance with the train-  
4 ing requirements described in subsection (g)(3) dur-  
5 ing any previous period in which the applicant has  
6 been subject to such training requirements.”.

7 (2) TRAINING REQUIREMENTS.—Section 303(g)  
8 of the Controlled Substances Act (21 U.S.C. 823(g))  
9 is amended by adding at the end the following:

10 “(3)(A) To be registered to prescribe or otherwise  
11 dispense methadone or other opioids, a practitioner de-  
12 scribed in paragraph (1) shall comply with the 16-hour  
13 training requirement of subparagraph (B) at least once  
14 during each 3-year period.

15 “(B) The training requirement of this subparagraph  
16 is that the practitioner has completed not less than 16  
17 hours of training (through classroom situations, seminars  
18 at professional society meetings, electronic communica-  
19 tions, or otherwise) with respect to—

20 “(i) the treatment and management of opioid-  
21 dependent patients;

22 “(ii) pain management treatment guidelines;  
23 and

1           “(iii) early detection of opioid addiction, includ-  
2           ing through such methods as Screening, Brief Inter-  
3           vention, and Referral to Treatment (SBIRT),  
4           that is provided by the American Society of Addiction  
5           Medicine, the American Academy of Addiction Psychiatry,  
6           the American Medical Association, the American Osteo-  
7           pathic Association, the American Psychiatric Association,  
8           the American Academy of Pain Management, the Amer-  
9           ican Pain Society, the American Academy of Pain Medi-  
10          cine, the American Board of Pain Medicine, the American  
11          Society of Interventional Pain Physicians, or any other or-  
12          ganization that the Secretary determines is appropriate  
13          for purposes of this subparagraph.”.

14          (b) REQUIREMENTS FOR PARTICIPATION IN OPIOID  
15          TREATMENT PROGRAMS.—Effective July 1, 2012, a phy-  
16          sician practicing in an opioid treatment program shall  
17          comply with the requirements of section 303(g)(3) of the  
18          Controlled Substances Act (as added by subsection (a))  
19          with respect to required minimum training at least once  
20          during each 3-year period.

21          (c) DEFINITION.—In this section, the term “opioid  
22          treatment program” has the meaning given such term in  
23          section 8.2 of title 42, Code of Federal Regulations (or  
24          any successor regulation).

1 (d) FUNDING.—The Drug Enforcement Administra-  
2 tion shall fund the enforcement of the requirements speci-  
3 fied in section 303(g)(3) of the Controlled Substances Act  
4 (as added by subsection (a)) through the use of a portion  
5 of the licensing fees paid by controlled substance pre-  
6 scribers under the Controlled Substances Act (21 U.S.C.  
7 801 et seq.).

8 **SEC. 5. MORATORIUM ON METHADONE HYDROCHLORIDE**  
9 **TABLETS.**

10 (a) IN GENERAL.—Notwithstanding any other provi-  
11 sion of law, during the period beginning on the date of  
12 enactment of this Act and ending on the date described  
13 in subsection (b), no individual or entity may prescribe  
14 or otherwise dispense a 40-mg diskette of methadone un-  
15 less such prescription or dispensation is consistent with  
16 the methadone 40-mg diskette policy of the Drug Enforce-  
17 ment Administration as in effect on the date of enactment  
18 of this Act, except that such prohibition shall extend to  
19 hospitals unless such hospitals provide for direct patient  
20 supervision with respect to such methadone.

21 (b) ENDING DATE OF MORATORIUM.—The morato-  
22 rium under subsection (a) shall cease to have force and  
23 effect—

24 (1) on the date that the Controlled Substances  
25 Clinical Standards Commission publishes in the Fed-



1       eral Register dosing guidelines for all forms of meth-  
2       adone, in accordance with section 506D(b)(1)(A) of  
3       the Public Health Service Act (as added by section  
4       7); and

5               (2) if, as part of such dosing guidelines, such  
6       Commission finds that 40-mg diskettes of metha-  
7       done are safe and clinically appropriate.

8       **SEC. 6. OPERATION OF OPIOID TREATMENT PROGRAMS.**

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

12       “(i)(1) An opioid treatment program that is reg-  
13     istered under this section, and that closes for business on  
14     any weekday or weekend day, including a Federal or State  
15     holiday, shall comply with the requirements of this sub-  
16     section.

17       “(2) The program shall make acceptable arrange-  
18     ments for each patient who is restricted, by Federal regu-  
19     lation or guideline or by the determination of the program  
20     medical director, from having a take home dose of a con-  
21     trolled substance related to the treatment involved, to re-  
22     ceive a dose of that substance under appropriate super-  
23     vision during the closure.

24       “(3) The Administrator of the Substance Abuse and  
25     Mental Health Services Administration shall issue a notice

1 that references regulations on acceptable arrangements  
 2 under this subsection, or shall promulgate regulations on  
 3 such acceptable arrangements.”.

4 **SEC. 7. ESTABLISHMENT OF THE CONTROLLED SUB-**  
 5 **STANCES CLINICAL STANDARDS COMMIS-**  
 6 **SION.**

7 Part A of title V of the Public Health Service Act  
 8 (42 U.S.C. 290aa et seq.), as amended by section 3, is  
 9 further amended by adding at the end the following:

10 **“SEC. 506D. ESTABLISHMENT OF THE CONTROLLED SUB-**  
 11 **STANCES CLINICAL STANDARDS COMMIS-**  
 12 **SION.**

13 “(a) IN GENERAL.—The Secretary shall establish a  
 14 Controlled Substances Clinical Standards Commission (re-  
 15 ferred to in this section as the ‘Commission’), to be com-  
 16 posed of representatives from the Administration, the Cen-  
 17 ters for Disease Control and Prevention, the Food and  
 18 Drug Administration, the Pain Management Consortia of  
 19 the National Institutes of Health, and other agencies that  
 20 the Secretary may deem necessary, to develop—

21 “(1) appropriate and safe dosing guidelines for  
 22 all forms of methadone, including recommendations  
 23 for maximum daily doses of all forms as provided for  
 24 in subsection (b)(1);

1           “(2) benchmark guidelines for the reduction of  
2 methadone abuse, as provided for in subsection  
3 (b)(2);

4           “(3) appropriate conversion factors for use by  
5 health care providers in transitioning patients from  
6 one opioid to another;

7           “(4) specific guidelines for initiating pain man-  
8 agement with methadone that prescribing practi-  
9 tioners shall comply with in order to meet certifi-  
10 cation requirements set forth in part C of the Con-  
11 trolled Substances Act (21 U.S.C. 821 et seq.); and

12           “(5) patient and practitioner education guide-  
13 lines for both methadone maintenance therapy and  
14 pain management that apply to safe and effective  
15 use and include detoxification.

16           “(b) GUIDELINES.—

17           “(1) PUBLICATION OF DOSING GUIDELINES.—

18           “(A) IN GENERAL.—Not later than 2 years  
19 after the date of enactment of this section, the  
20 Commission established under subsection (a)  
21 shall publish in the Federal Register—

22           “(i) safe and clinically appropriate  
23 dosing guidelines for all forms of metha-  
24 done used for both pain management and  
25 opioid treatment programs, including rec-

1           ommendations for maximum daily doses of  
2           all forms, including recommendations for  
3           the induction process for patients who are  
4           newly prescribed methadone;

5           “(ii) requirements for individual pa-  
6           tient care plans, including initial and fol-  
7           low-up patient physical examination guide-  
8           lines, and recommendations for screening  
9           patients for chronic or acute medical condi-  
10          tions that may cause an immediate and ad-  
11          verse reaction to methadone;

12          “(iii) appropriate conversion factors  
13          for use by health care providers in  
14          transitioning patients from one opioid to  
15          another;

16          “(iv) specific guidelines for initiating  
17          pain management with methadone, that  
18          prescribing physicians or other clinicians  
19          shall comply with in order to meet Drug  
20          Enforcement Administration certification  
21          and re-certification requirements; and

22          “(v) consensus guidelines for pain  
23          management with prescription opioid  
24          drugs.

1           “(B) UPDATING OF GUIDELINES.—Not  
2 later than 3 years after the publication of  
3 guidelines under subparagraph (A), and at least  
4 every 3 years thereafter, the Commission shall  
5 update such guidelines.

6           “(2) PUBLICATION OF BENCHMARK GUIDE-  
7 LINES.—

8           “(A) IN GENERAL.—Not later than 3 years  
9 after the date of enactment of this section, the  
10 Commission established under subsection (a)  
11 shall publish in the Federal Register—

12                   “(i) the initial benchmark guidelines  
13 for the reduction of methadone abuse to be  
14 used—

15                           “(I) by opioid treatment pro-  
16 grams in providing methadone ther-  
17 apy; and

18                           “(II) by entities in the initial ac-  
19 creditation or certification, and the re-  
20 accreditation and re-certification, of  
21 such opioid treatment programs;

22                           “(ii) a model policy for dispensing  
23 methadone to be used by pharmacists that  
24 dispense methadone, which should include

1 education and training guidelines for such  
2 pharmacists;

3 “(iii) the continuing education guide-  
4 lines that all prescribers shall comply with  
5 in order to meet Drug Enforcement Ad-  
6 ministration certification and re-certifi-  
7 cation requirements, as set forth in section  
8 303(g)(3) of the Controlled Substances Act  
9 (21 U.S.C. 823(g)(3)), which should in-  
10 clude a minimum of 16 training hours at  
11 least every 3 years that include the inte-  
12 gration of both addiction and pain man-  
13 agement curricula; and

14 “(iv) patient education guidelines for  
15 both opioid treatment programs and pain  
16 management, including recommendations  
17 for patient counseling prior to and during  
18 opioid addiction treatment or treatment for  
19 pain.

20 “(B) UPDATING OF GUIDELINES.—Not  
21 later than 1 year after the publication of guide-  
22 lines under subparagraph (A), and at least an-  
23 nually thereafter, the Commission shall update  
24 the guidelines published under clauses (iii) and  
25 (iv) of such subparagraph.

1           “(3) CONSULTATION.—In developing and pub-  
2           lishing the guidelines under this section, the Com-  
3           mission shall consult with relevant professional orga-  
4           nizations with expertise in the area of addiction, rel-  
5           evant professional organizations with expertise in the  
6           area of pain management, physician groups, phar-  
7           macy groups (including the National Association of  
8           Boards of Pharmacy), patient representatives, and  
9           any other organization that the Secretary determines  
10          is appropriate for purposes of this section.

11          “(c) WEBSITE.—Not later than 180 days after the  
12          date of enactment of this section, the Commission shall  
13          establish and operate a Commission website.

14          “(d) METHADONE TOOLKIT.—Not later than 1 year  
15          after the date of enactment of this section, the Commis-  
16          sion shall establish, and distribute to practitioners that are  
17          registered to prescribe or otherwise dispense methadone,  
18          a methadone toolkit. The Commission shall make the com-  
19          ponents of the toolkit that are available in electronic form  
20          available on the Commission website.

21          “(e) PRACTITIONER EDUCATION PROGRAM.—The  
22          Commission shall develop a practitioner education pro-  
23          gram that shall be used for the practitioner education de-  
24          scribed in section 303(g)(3) of the Controlled Substances

1 Act, and shall make such program available to providers  
2 of such practitioner education.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
4 is authorized to be appropriated to carry out this section  
5 such sums as may be necessary for each of fiscal years  
6 2012 through 2016.”.

7 **SEC. 8. PRESCRIPTION MONITORING PROGRAM.**

8 Section 3990 of the Public Health Service Act (42  
9 U.S.C. 280g–3) is amended—

10 (1) in subsection (d)(1), by inserting “(includ-  
11 ing prescribers of methadone)” after “dispensers”;

12 (2) in subsection (e), by adding at the end the  
13 following:

14 “(5) Subject to the requirements of section 543,  
15 the State shall, at the request of a Federal, State,  
16 or local officer whose duties include enforcing laws  
17 relating to drugs, provide to such officer information  
18 from the database relating to an individual who is  
19 the subject of an active drug-related investigation  
20 conducted by the officer’s employing government en-  
21 tity.”; and

22 (3) by striking subsection (n) and inserting the  
23 following:



1       “(n) APPROPRIATIONS.—There is authorized to be  
2 appropriated to carry out this section \$25,000,000 for  
3 each of fiscal years 2012 through 2016.”.

4 **SEC. 9. MORTALITY REPORTING.**

5       Part A of title V of the Public Health Service Act  
6 (42 U.S.C. 290aa et seq.), as amended by section 7, is  
7 further amended by adding at the end the following:

8 **“SEC. 506E. MORTALITY REPORTING.**

9       “(a) MODEL OPIOID TREATMENT PROGRAM MOR-  
10 TALITY REPORT.—

11           “(1) IN GENERAL.—Not later than July 1,  
12 2012, the Secretary, acting through the Adminis-  
13 trator, shall require that a Model Opioid Treatment  
14 Program Mortality Report be completed and sub-  
15 mitted to the Administrator for each individual who  
16 dies while receiving treatment in an opioid treatment  
17 program.

18           “(2) REQUIREMENT OF STATES THAT RECEIVE  
19 FUNDING FOR THE CONTROLLED SUBSTANCE MONI-  
20 TORING PROGRAM.—As a condition for receiving  
21 funds under section 3990, each State shall require  
22 that any individual who signs a death certificate  
23 where an opioid drug is detected in the body of the  
24 deceased, or where such drug is otherwise associated  
25 with the death, report such death to the Adminis-

1 trator by submitting a Model Opioid Treatment Pro-  
2 gram Mortality Report described in paragraph (3).  
3 Such report shall be submitted to the Administrator  
4 on or before the later of—

5 “(A) 90 days after the date of signing the  
6 death certificate; or

7 “(B) as soon as practicable after the date  
8 on which the necessary postmortem and toxico-  
9 logy reports become available to such indi-  
10 vidual, as required by the Secretary.

11 “(3) DEVELOPMENT.—The Administrator, in  
12 consultation with State and local medical examiners,  
13 prescribing physicians, hospitals, and any other or-  
14 ganization that the Administrator determines appro-  
15 priate, shall develop a Model Opioid Treatment Pro-  
16 gram Mortality Report to be used under paragraphs  
17 (1) and (2).

18 “(b) NATIONAL OPIOID DEATH REGISTRY.—

19 “(1) IN GENERAL.—Not later than July 1,  
20 2012, the Administrator shall establish and imple-  
21 ment, through the National Center for Health Sta-  
22 tistics, a National Opioid Death Registry (referred  
23 to in this subsection as the ‘Registry’) to track  
24 opioid-related deaths and information related to such  
25 deaths.

1           “(2) CONSULTATION.—In establishing the uni-  
2 form reporting criteria for the Registry, the Director  
3 of the Centers for Disease Control and Prevention  
4 shall consult with the Administrator, State and local  
5 medical examiners, prescribing physicians, hospitals,  
6 and any other organization that the Director deter-  
7 mines is appropriate for purposes of this subsection.

8           “(3) REQUIREMENTS.—The registry shall be  
9 designed as a uniform reporting system for opioid-  
10 related deaths and shall require the reporting of in-  
11 formation with respect to such deaths, including—

12                   “(A) the particular drug formulation used  
13 at the time of death;

14                   “(B) the dosage level;

15                   “(C) a description of the circumstances  
16 surrounding the death in relation to the rec-  
17 ommended dosage involved;

18                   “(D) a disclosure of whether the medica-  
19 tion involved can be traced back to a physi-  
20 cian’s prescription;

21                   “(E) a disclosure of whether the individual  
22 was in an opioid treatment program at the time  
23 of death;

24                   “(F) the age and sex of the individual; and

1           “(G) other non-personal information such  
2           as that included in filed National Association of  
3           Medical Examiners Pediatric Toxicology Reg-  
4           istry case reports as required under the privacy  
5           standard for the de-identification of health in-  
6           formation pursuant to the regulations contained  
7           in part 164 of title 45, Code of Federal Regula-  
8           tions.

9           “(4) AUTHORIZATION.—There is authorized to  
10          be appropriated \$5,000,000 for each of fiscal years  
11          2012 through 2016 to carry out this subsection.

12          “(c) REPORT ON REGISTRY INFORMATION.—Not  
13          later than the January 1 of the first fiscal year beginning  
14          2 years after the date of enactment of this section, and  
15          each January 1 thereafter, the Director of the Centers for  
16          Disease Control and Prevention shall submit to the Sec-  
17          retary a report, based on information contained in the  
18          Registry described in subsection (b), concerning the num-  
19          ber of methadone-related deaths in the United States for  
20          the year for which the report is submitted.”.

21          **SEC. 10. ADDITIONAL REPORTING.**

22          Part A of title V of the Public Health Service Act  
23          (42 U.S.C. 290aa et seq.), as amended by section 9, is  
24          further amended by adding at the end the following:

1 **“SEC. 506F. ADDITIONAL REPORTING.**

2 “(a) REPORT ON METHADONE USAGE.—

3 “(1) IN GENERAL.—Not later than January 1  
4 of the first fiscal year beginning 2 years after the  
5 date of enactment of this section, and each January  
6 1 thereafter, the Administrator and the Commis-  
7 sioner of Food and Drugs shall submit to the Sec-  
8 retary a report containing detailed statistics on  
9 methadone usage for opioid treatment and pain  
10 management. Such statistics shall include—

11 “(A) information on the distribution of  
12 prescribed doses of methadone at federally  
13 qualified health centers, opioid treatment clin-  
14 ics, other health-related clinics, physician of-  
15 fices, pharmacies, and hospitals; and

16 “(B) information relating to adverse health  
17 events resulting from such methadone usage.

18 “(2) AVAILABILITY OF INFORMATION.—The  
19 Secretary shall make the reports submitted under  
20 paragraph (1) available to the general public, includ-  
21 ing through the use of the Internet website of the  
22 Department of Health and Human Services.

23 “(b) ANNUAL REPORT ON EFFECTIVENESS.—Not  
24 later than September 30, 2012, and annually thereafter  
25 until September 30, 2016, the Secretary shall submit to  
26 the appropriate committees of Congress, a report con-

1 cerning the effectiveness of the methadone maintenance  
2 therapy program. Such report shall evaluate the success  
3 of efforts to reduce opioid addiction and methadone-re-  
4 lated deaths, including the impact of health care provider  
5 and patient education.

6 “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
7 is authorized to be appropriated to carry out this section  
8 such sums as may be necessary for each of fiscal years  
9 2012 through 2016.”.

○