

111TH CONGRESS
1ST SESSION

S. 754

To provide for increased Federal oversight of methadone treatment.

IN THE SENATE OF THE UNITED STATES

MARCH 31, 2009

Mr. ROCKEFELLER (for himself, Mr. CORKER, and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for increased Federal oversight of methadone treatment.

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 “Methadone Treatment
5 and Protection Act of 2009”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

8 (1) Methadone is an extensively tested, federally
9 approved, and widely accepted method of effective
10 treatment.

1 (2) For more than 30 years, this synthetic pre-
2 scription drug has been used for pain management
3 and treatment for addiction to heroin, morphine,
4 and other opioid drugs.

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

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

10 (5) As with any controlled substance, there is a
11 risk of abuse of methadone.

12 (6) According to the Centers for Disease Con-
13 trol and Prevention, in 2005, there were 4,462
14 methadone-related deaths, representing an increase
15 of 468 percent since 1999. By contrast, all poisoning
16 deaths by all drugs increased by 66 percent over the
17 same period.

18 (7) The age-specific rates of methadone death
19 are higher for persons age 35 to 44 and 45 to 54
20 than for other age groups. However, the rate of
21 methadone deaths in younger individuals (age 15 to
22 24) increased 11-fold from 1999 through 2005.

23 (8) Deaths from methadone may actually be
24 underreported. There is no comprehensive database
25 of drug-related deaths in the United States.

1 (9) The lack of standardized reporting by Med-
 2 ical Examiners precludes a uniform definition of
 3 “cause of death” on death certificates.

4 (10) While the Controlled Substances Act (21
 5 U.S.C. 801 et seq.) requires additional registration
 6 for practitioners who dispense schedule II narcotics,
 7 including methadone, for both pain management and
 8 addiction treatment, there is no specific education
 9 requirements for practitioners to prescribe metha-
 10 done for pain management.

11 (11) Current Federal oversight of methadone is
 12 inadequate to address the growing number of metha-
 13 done-related deaths.

14 (12) Federal legislation is needed to increase
 15 Federal oversight over methadone treatment, both as
 16 part of opioid treatment programs and as part of
 17 the treatment of pain, without reducing patient ac-
 18 cess.

19 **SEC. 3. CONSUMER EDUCATION CAMPAIGN.**

20 Part A of title V of the Public Health Service Act
 21 (42 U.S.C. 290aa et seq.) is amended by adding at the
 22 end the following:

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

24 “(a) IN GENERAL.—The Administrator shall award
 25 grants to States and nonprofit community organizations

1 for the purpose of educating consumers about the dangers
 2 of opioid abuse, including methadone abuse, through edu-
 3 cational materials that are culturally sensitive.

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

6 “(1) be a State or nonprofit community organi-
 7 zation; and

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

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

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 2010 through 2014.”.

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 opiate-
21 dependent patients; and

22 “(ii) pain management treatment guidelines,
23 that is provided by the American Society of Addiction
24 Medicine, the American Academy of Addiction Psychiatry,
25 the American Medical Association, the American Osteo-

1 pathic Association, the American Psychiatric Association,
 2 the American Academy of Pain Management, the Amer-
 3 ican Pain Society, the American Academy of Pain Medi-
 4 cine, the American Board of Pain Medicine, or any other
 5 organization that the Secretary determines is appropriate
 6 for purposes of this subparagraph.”.

7 (b) REQUIREMENTS FOR PARTICIPATION IN OPIOID
 8 TREATMENT PROGRAMS.—Effective July 1, 2009, a phy-
 9 sician practicing in an opioid treatment program shall
 10 comply with the requirements of section 303(g)(3) of the
 11 Controlled Substances Act (as added by subsection (a))
 12 with respect to required minimum training at least once
 13 during each 3-year period.

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

18 (d) FUNDING.—The Drug Enforcement Administra-
 19 tion shall fund the enforcement of the requirements speci-
 20 fied in section 303(g)(3) of the Controlled Substances Act
 21 (as added by subsection (a)) through the use of a portion
 22 of the licensing fees paid by controlled substance pre-
 23 scribers under the Controlled Substances Act (21 U.S.C.
 24 801 et seq.).

1 **SEC. 5. MORATORIUM ON METHADONE HYDROCHLORIDE**
2 **TABLETS.**

3 (a) IN GENERAL.—Notwithstanding any other provi-
4 sion of law, during the period beginning on the date of
5 enactment of this Act and ending on the date described
6 in subsection (b), no individual or entity may prescribe
7 or otherwise dispense a 40-mg diskette of methadone un-
8 less such prescription or dispensation is consistent with
9 the methadone policy implemented by the Drug Enforce-
10 ment Administration on the date of enactment of this Act,
11 except that such prohibition shall extend to opioid treat-
12 ment programs and hospitals unless such programs or
13 hospitals provide for direct patient supervision with re-
14 spect to such methadone. During such period, no take
15 home dosages of 40-mg diskettes of methadone shall be
16 permitted.

17 (b) ENDING DATE OF MORATORIUM.—The morato-
18 rium under subsection (a) shall cease to have force and
19 effect—

20 (1) on the date that the Controlled Substances
21 Clinical Standards Commission publishes in the Fed-
22 eral Register dosing standards for all forms of meth-
23 adone, in accordance with section 506D(b)(1)(A) of
24 the Public Health Service Act (as added by section
25 7); and

1 (2) if, as part of such dosing standards, such
2 Commission finds that 40-mg diskettes of metha-
3 done are safe and clinically appropriate.

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

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

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

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

20 “(3) The Administrator of the Substance Abuse and
21 Mental Health Services Administration shall issue a notice
22 that references regulations on acceptable arrangements
23 under this subsection, or shall promulgate regulations on
24 such acceptable arrangements.”.

1 **SEC. 7. ESTABLISHMENT OF THE CONTROLLED SUB-**
 2 **STANCES CLINICAL STANDARDS COMMIS-**
 3 **SION.**

4 Part A of title V of the Public Health Service Act
 5 (42 U.S.C. 290aa et seq.), as amended by section 3, is
 6 further amended by adding at the end the following:

7 **“SEC. 506D. ESTABLISHMENT OF THE CONTROLLED SUB-**
 8 **STANCES CLINICAL STANDARDS COMMIS-**
 9 **SION.**

10 “(a) IN GENERAL.—The Secretary shall establish a
 11 Controlled Substances Clinical Standards Commission (re-
 12 ferred to in this section as the ‘Commission’), to be com-
 13 posed of representatives from the Administration, the Cen-
 14 ters for Disease Control and Prevention, the Food and
 15 Drug Administration, and the Pain Management Con-
 16 sortia of the National Institutes of Health, to develop—

17 “(1) appropriate and safe dosing standards for
 18 all forms of methadone, including recommendations
 19 for maximum daily doses of all forms as provided for
 20 in subsection (b)(1);

21 “(2) benchmark standards for the reduction of
 22 methadone abuse, as provided for in subsection
 23 (b)(2);

24 “(3) appropriate conversion factors for use by
 25 health care providers in transitioning patients from
 26 one opioid to another;

1 “(4) specific guidelines for initiating pain man-
2 agement with methadone that prescribing physicians
3 shall comply with in order to meet certification re-
4 quirements set forth in part C of the Controlled
5 Substances Act (21 U.S.C. 821 et seq.); and

6 “(5) patient and practitioner education stand-
7 ards for both methadone maintenance therapy and
8 pain management that apply to safe and effective
9 use and include detoxification.

10 “(b) STANDARDS.—

11 “(1) PUBLICATION OF DOSING STANDARDS.—

12 “(A) IN GENERAL.—Not later than 2 years
13 after the date of enactment of the Methadone
14 Treatment and Protection Act of 2009, the
15 Commission established under subsection (a)
16 shall publish in the Federal Register—

17 “(i) safe and clinically appropriate
18 dosing standards for all forms of metha-
19 done used for both pain management and
20 opioid treatment programs, including rec-
21 ommendations for maximum daily doses of
22 all forms, including recommendations for
23 the induction process for patients who are
24 newly prescribed methadone;

1 “(ii) requirements for individual pa-
2 tient care plans, including initial and fol-
3 low-up patient physical examination stand-
4 ards, and recommendations for screening
5 patients for chronic or acute medical condi-
6 tions that may cause an immediate and ad-
7 verse reaction to methadone;

8 “(iii) appropriate conversion factors
9 for use by health care providers in
10 transitioning patients from one opioid to
11 another; and

12 “(iv) specific guidelines for initiating
13 pain management with methadone, that
14 prescribing physicians shall comply with in
15 order to meet Drug Enforcement Adminis-
16 tration certification and re-certification re-
17 quirements.

18 “(B) UPDATING OF STANDARDS.—Not
19 later than 3 years after the publication of
20 standards under subparagraph (A), and at least
21 every 3 years thereafter, the Commission shall
22 update such standards.

23 “(2) PUBLICATION OF BENCHMARK STAND-
24 ARDS.—

1 “(A) IN GENERAL.—Not later than 3 years
2 after the date of enactment of the Methadone
3 Treatment and Protection Act of 2009, the
4 Commission established under subsection (a)
5 shall publish in the Federal Register—

6 “(i) the initial benchmark standards
7 for the reduction of methadone abuse to be
8 used—

9 “(I) by opioid treatment pro-
10 grams in providing methadone ther-
11 apy; and

12 “(II) by entities in the initial ac-
13 creditation or certification, and the re-
14 accreditation and re-certification, of
15 such opioid treatment programs;

16 “(ii) a model policy for dispensing
17 methadone to be used by pharmacists that
18 dispense methadone, which should include
19 education and training standards for such
20 pharmacists;

21 “(iii) the continuing education stand-
22 ards that all prescribers shall comply with
23 in order to meet Drug Enforcement Ad-
24 ministration certification and re-certifi-
25 cation requirements, as set forth in section

1 303(g)(3) of the Controlled Substances Act
2 (21 U.S.C. 823(g)(3)), which should in-
3 clude a minimum of 16 training hours at
4 least every 3 years that include the inte-
5 gration of both addiction and pain man-
6 agement curricula; and

7 “(iv) patient education standards for
8 both opioid treatment programs and pain
9 management, including recommendations
10 for patient counseling prior to and during
11 opioid addiction treatment or treatment for
12 pain.

13 “(B) UPDATING OF STANDARDS.—Not
14 later than 1 year after the publication of stand-
15 ards under subparagraph (A), and at least an-
16 nually thereafter, the Commission shall update
17 the standards published under clauses (iii) and
18 (iv) of such subparagraph.

19 “(3) CONSULTATION.—In developing and pub-
20 lishing the standards under this section, the Com-
21 mission shall consult with relevant professional orga-
22 nizations with expertise in the area of addiction, rel-
23 evant professional organizations with expertise in the
24 area of pain management, physician groups, phar-
25 macy groups (including the National Association of

1 Boards of Pharmacy), and any other organization
2 that the Secretary determines is appropriate for pur-
3 poses of this section.

4 “(c) WEBSITE.—Not later than 180 days after the
5 date of enactment of the Methadone Treatment and Pro-
6 tection Act of 2009, the Commission shall establish and
7 operate a Commission website.

8 “(d) METHADONE TOOLKIT.—Not later than 180
9 days after the date of enactment of the Methadone Treat-
10 ment and Protection Act of 2009, the Commission shall
11 establish, and distribute to practitioners that are reg-
12 istered to prescribe or otherwise dispense methadone, a
13 methadone toolkit. The Commission shall make the com-
14 ponents of the toolkit that are available in electronic form
15 available on the Commission website.

16 “(e) PRACTITIONER EDUCATION PROGRAM.—The
17 Commission shall develop a practitioner education pro-
18 gram that shall be used for the practitioner education de-
19 scribed in section 303(g)(3) of the Controlled Substances
20 Act, and shall make such program available to providers
21 of such practitioner education.

22 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
23 is authorized to be appropriated to carry out this section
24 such sums as may be necessary for each of fiscal years
25 2010 through 2014.”.

1 **SEC. 8. PRESCRIPTION MONITORING PROGRAM.**

2 Section 399O of the Public Health Service Act (42
3 U.S.C. 280g–3) is amended—

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

6 (2) in subsection (e), by adding at the end the
7 following:

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

16 (3) by striking subsection (n) and inserting the
17 following:

18 “(n) APPROPRIATIONS.—There is authorized to be
19 appropriated, and there is appropriated, to carry out this
20 section \$25,000,000 for each of fiscal years 2010 through
21 2014.”.

22 **SEC. 9. MORTALITY REPORTING.**

23 Part A of title V of the Public Health Service Act
24 (42 U.S.C. 290aa et seq.), as amended by section 7, is
25 further amended by adding at the end the following:

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

2 “(a) MODEL OPIOID TREATMENT PROGRAM MOR-
3 TALITY REPORT.—

4 “(1) IN GENERAL.—Not later than October 1,
5 2009, the Secretary, acting through the Adminis-
6 trator, shall require that a Model Opioid Treatment
7 Program Mortality Report be completed and sub-
8 mitted to the Administrator for each individual who
9 dies while receiving treatment in an opioid treatment
10 program.

11 “(2) REQUIREMENT OF STATES THAT RECEIVE
12 FUNDING FOR THE CONTROLLED SUBSTANCE MONI-
13 TORING PROGRAM.—As a condition for receiving
14 funds under section 399O, each State shall require
15 that any individual who signs a death certificate
16 where an opioid drug is detected in the body of the
17 deceased, or where such drug is otherwise associated
18 with the death, report such death to the Adminis-
19 trator by submitting a Model Opioid Treatment Pro-
20 gram Mortality Report described in paragraph (3).
21 Such report shall be submitted to the Administrator
22 on or before the later of—

23 “(A) 90 days after the date of signing the
24 death certificate; or

25 “(B) as soon as practicable after the date
26 on which the necessary postmortem and toxi-

1 cology reports become available to such indi-
2 vidual, as required by the Secretary.

3 “(3) DEVELOPMENT.—The Administrator, in
4 consultation with State and local medical examiners,
5 prescribing physicians, hospitals, and any other or-
6 ganization that the Administrator determines appro-
7 priate, shall develop a Model Opioid Treatment Pro-
8 gram Mortality Report to be used under paragraphs
9 (1) and (2).

10 “(b) NATIONAL OPIOID DEATH REGISTRY.—

11 “(1) IN GENERAL.—Not later than January 1,
12 2010, the Administrator shall establish and imple-
13 ment, through the National Center for Health Sta-
14 tistics, a National Opioid Death Registry (referred
15 to in this subsection as the ‘Registry’) to track all
16 aPD-related deaths and information related to such
17 deaths.

18 “(2) CONSULTATION.—In establishing the uni-
19 form reporting criteria for the Registry, the Director
20 of the Centers for Disease Control and Prevention
21 shall consult with the Administrator, State and local
22 medical examiners, prescribing physicians, hospitals,
23 and any other organization that the Director deter-
24 mines is appropriate for purposes of this subsection.

1 “(3) REQUIREMENTS.—The registry shall be
2 designed as a uniform reporting system for aPD-re-
3 lated deaths and shall require the reporting of infor-
4 mation with respect to each such death, including—

5 “(A) the particular drug formulation used
6 at the time of death;

7 “(B) the dosage level;

8 “(C) a description of the circumstances
9 surrounding the death in relation to the rec-
10 ommended dosage involved;

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

14 “(E) a disclosure of whether the individual
15 was in an opioid treatment program at the time
16 of death;

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

18 “(G) other non-personal information such
19 as that included in filed National Association of
20 Medical Examiners Pediatric Toxicology Reg-
21 istry (paddies) case reports as required under
22 the privacy standard for the de-identification of
23 health information pursuant to the regulations
24 contained in part 164 of title 45, Code of Fed-
25 eral Regulations.

1 “(4) AUTHORIZATION.—There is authorized to
2 be appropriated \$5,000,000 to carry out this sub-
3 section.

4 “(c) REPORT ON REGISTRY INFORMATION.—Not
5 later than the January 1 of the first fiscal year beginning
6 2 years after the date of enactment of the Methadone
7 Treatment and Protection Act of 2009, and each January
8 1 thereafter, the Director of the Centers for Disease Con-
9 trol and Prevention shall submit to the Secretary a report,
10 based on information contained in the Registry described
11 in subsection (b), concerning the number of methadone-
12 related deaths in the United States for the year for which
13 the report is submitted.”.

14 **SEC. 10. ADDITIONAL REPORTING.**

15 Part A of title V of the Public Health Service Act
16 (42 U.S.C. 290aa et seq.), as amended by section 9, is
17 further amended by adding at the end the following:

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

19 “(a) REPORT ON METHADONE USAGE.—

20 “(1) IN GENERAL.—Not later than January 1
21 of the first fiscal year beginning 2 years after the
22 date of enactment of the Methadone Treatment and
23 Protection Act of 2009, and each January 1 there-
24 after, the Administrator shall submit to the Sec-
25 retary a report containing detailed statistics on

1 methadone usage for opioid treatment and pain
2 management. Such statistics shall include—

3 “(A) information on the distribution of
4 prescribed doses of methadone at federally
5 qualified health centers, opioid treatment clin-
6 ics, other health-related clinics, physician of-
7 fices, pharmacies, and hospitals; and

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

10 “(2) AVAILABILITY OF INFORMATION.—The
11 Secretary shall make the reports submitted under
12 paragraph (1) available to the general public, includ-
13 ing through the use of the Internet website of the
14 Department of Health and Human Services.

15 “(b) ANNUAL REPORT ON EFFECTIVENESS.—Not
16 later than September 30, 2010, and annually thereafter
17 until September 30, 2014, the Secretary shall submit to
18 the appropriate committees of Congress, a report con-
19 cerning the effectiveness of the methadone maintenance
20 therapy program. Such report shall evaluate the success
21 of efforts to reduce opioid addiction and methadone-re-
22 lated deaths, including the impact of health care provider
23 and patient education.

24 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
25 is authorized to be appropriated to carry out this section

- 1 such sums as may be necessary for each of fiscal years
- 2 2010 through 2014.”.

