

Calendar No. 440

114TH CONGRESS
2D SESSION

S. 480

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2015

Mrs. SHAHEEN (for herself, Mr. TOOMEY, Mr. DURBIN, Mr. SESSIONS, Mr. BROWN, Mrs. FEINSTEIN, Mrs. GILLIBRAND, Mr. MANCHIN, Mr. MARKEY, Mr. SCHUMER, Ms. WARREN, Mr. BLUMENTHAL, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 27, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “National All Schedules
3 Prescription Electronic Reporting Reauthorization Act of
4 2015”.

5 **SEC. 2. AMENDMENT TO PURPOSE.**

6 Paragraph (1) of section 2 of the National All Sched-
7 ules Prescription Electronic Reporting Act of 2005 (Public
8 Law 109–60) is amended to read as follows:

9 “(1) foster the establishment of State-adminis-
10 tered controlled substance monitoring systems in
11 order to ensure that—

12 “(A) health care providers have access to
13 the accurate, timely prescription history infor-
14 mation that they may use as a tool for the early
15 identification of patients at risk for addiction in
16 order to initiate appropriate medical interven-
17 tions and avert the tragic personal, family, and
18 community consequences of untreated addiction;
19 and

20 “(B) appropriate law enforcement, regu-
21 latory, and State professional licensing authori-
22 ties have access to prescription history informa-
23 tion for the purposes of investigating drug di-
24 version and prescribing and dispensing prac-
25 tices of errant prescribers or pharmacists; and”.

1 **SEC. 3. AMENDMENTS TO CONTROLLED SUBSTANCE MONI-**
 2 **TORING PROGRAM.**

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

5 (1) in subsection (a)(1)—

6 (A) in subparagraph (A), by striking “or”;

7 (B) in subparagraph (B), by striking the
 8 period at the end and inserting “; or”; and

9 (C) by adding at the end the following:

10 “(C) to maintain and operate an existing
 11 State-controlled substance monitoring pro-
 12 gram.”;

13 (2) by amending subsection (b) to read as fol-
 14 lows:

15 “(b) **MINIMUM REQUIREMENTS.**—The Secretary
 16 shall maintain and, as appropriate, supplement or revise
 17 (after publishing proposed additions and revisions in the
 18 Federal Register and receiving public comments thereon)
 19 minimum requirements for criteria to be used by States
 20 for purposes of clauses (ii), (v), (vi), and (vii) of subsection
 21 (c)(1)(A).”;

22 (3) in subsection (c)—

23 (A) in paragraph (1)(B)—

24 (i) in the matter preceding clause (i),

25 by striking “(a)(1)(B)” and inserting

26 “(a)(1)(B) or (a)(1)(C)”;

(ii) in clause (i), by striking “program to be improved” and inserting “program to be improved or maintained”;

(iii) by redesignating clauses (iii) and (iv) as clauses (iv) and (v), respectively;

(iv) by inserting after clause (ii), the following:

“(iii) a plan to apply the latest advances in health information technology in order to incorporate prescription drug monitoring program data directly into the workflow of prescribers and dispensers to ensure timely access to patients’ controlled prescription drug history;”;

(v) in clause (iv) (as so redesignated), by inserting before the semicolon the following: “and at least one health information technology system such as electronic health records, health information exchanges, and e-prescribing systems”; and

(vi) in clause (v) (as so redesignated), by striking “public health” and inserting “public health or public safety”;

(B) in paragraph (3)—

1 (i) by striking “If a State that sub-
 2 mits” and inserting the following:

3 “(A) IN GENERAL.—If a State that sub-
 4 mits”;

5 (ii) by inserting before the period at
 6 the end “and include timelines for full im-
 7 plementation of such interoperability. The
 8 State shall also describe the manner in
 9 which it will achieve interoperability be-
 10 tween its monitoring program and health
 11 information technology systems, as allow-
 12 able under State law, and include timelines
 13 for the implementation of such interoper-
 14 ability”; and

15 (iii) by adding at the end the fol-
 16 lowing:

17 “(B) MONITORING OF EFFORTS.—The
 18 Secretary shall monitor State efforts to achieve
 19 interoperability, as described in subparagraph
 20 (A).”; and

21 (C) in paragraph (5)—

22 (i) by striking “implement or im-
 23 prove” and inserting “establish, improve,
 24 or maintain”; and

(ii) by adding at the end the following: “The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).”;

(4) in subsection (d)—

(A) in the matter preceding paragraph (1)—

(i) by striking “In implementing or improving” and all that follows through “(a)(1)(B)” and inserting “In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)”;

(ii) by striking “public health” and inserting “public health or public safety”;

and

(B) by adding at the end the following:

“(5) The State shall report on interoperability with the controlled substance monitoring program of Federal agencies, where appropriate, interoperability

1 with health information technology systems such as
 2 electronic health records, health information ex-
 3 changes, and e-prescribing, where appropriate, and
 4 whether or not the State provides automatic, real-
 5 time or daily information about a patient when a
 6 practitioner (or the designee of a practitioner, where
 7 permitted) requests information about such pa-
 8 tient.”;

9 (5) in subsections (c), (f)(1), and (g), by strik-
 10 ing “implementing or improving” each place it ap-
 11 pears and inserting “establishing, improving, or
 12 maintaining”;

13 (6) in subsection (f)—

14 (A) in paragraph (1)(B) by striking “mis-
 15 use of a schedule II, III, or IV substance” and
 16 inserting “misuse of a controlled substance in-
 17 cluded in schedule II, III, or IV of section
 18 202(e) of the Controlled Substance Act”; and

19 (B) by adding at the end the following:

20 “(3) EVALUATION AND REPORTING.—Subject
 21 to subsection (g), a State receiving a grant under
 22 subsection (a) shall provide the Secretary with ag-
 23 gregate data and other information determined by
 24 the Secretary to be necessary to enable the Sec-
 25 retary—

1 “(A) to evaluate the success of the State’s
2 program in achieving its purposes; or

3 “(B) to prepare and submit the report to
4 Congress required by subsection (k)(2).

5 “(4) RESEARCH BY OTHER ENTITIES.—A de-
6 partment, program, or administration receiving non-
7 identifiable information under paragraph (1)(D)
8 may make such information available to other enti-
9 ties for research purposes.”;

10 (7) by striking subsection (k);

11 (8) by redesignating subsections (h) through (j)
12 as subsections (i) through (k), respectively;

13 (9) in subsections (c)(1)(A)(iv) and (d)(4), by
14 striking “subsection (h)” each place it appears and
15 inserting “subsection (i)”;

16 (10) by inserting after subsection (g) the fol-
17 lowing:

18 “(h) EDUCATION AND ACCESS TO THE MONITORING
19 SYSTEM.—A State receiving a grant under subsection (a)
20 shall take steps to—

21 “(1) facilitate prescriber and dispenser use of
22 the State’s controlled substance monitoring system;
23 and

24 “(2) educate prescribers and dispenser on the
25 benefits of the system both to them and society.”;

1 ~~(11)~~ in subsection ~~(k)~~(2)(A), as redesignated—

2 (A) in clause (ii), by striking “or affected”

3 and inserting “; established or strengthened ini-

4 tiatives to ensure linkages to substance use dis-

5 order services; or affected”; and

6 (B) in clause (iii), by striking “including

7 an assessment” and inserting “between con-

8 trolled substance monitoring programs and

9 health information technology systems; and in-

10 cluding an assessment”;

11 ~~(12)~~ in subsection ~~(l)~~(1), by striking “establish-

12 ment, implementation, or improvement” and insert-

13 ing “establishment, improvement, or maintenance”;

14 ~~(13)~~ in subsection ~~(m)~~(8), by striking “and the

15 District of Columbia” and inserting “; the District

16 of Columbia; and any commonwealth or territory of

17 the United States”; and

18 ~~(14)~~ by amending subsection ~~(n)~~, to read as fol-

19 lows:

20 “(o) AUTHORIZATION OF APPROPRIATIONS.—To

21 carry out this section, there are authorized to be appro-

22 priated \$7,000,000 for each of fiscal years 2016 through

23 2020.”.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “National All Schedules*
 3 *Prescription Electronic Reporting Reauthorization Act of*
 4 *2016”.*

5 **SEC. 2. AMENDMENT TO PURPOSE.**

6 *Paragraph (1) of section 2 of the National All Sched-*
 7 *ules Prescription Electronic Reporting Act of 2005 (Public*
 8 *Law 109–60) is amended to read as follows:*

9 *“(1) foster the establishment of State-adminis-*
 10 *tered controlled substance monitoring systems in*
 11 *order to ensure that health care providers have access*
 12 *to the accurate, timely prescription history informa-*
 13 *tion that they may use as a tool for the early identi-*
 14 *fication of patients at risk for addiction in order to*
 15 *initiate appropriate medical interventions and avert*
 16 *the tragic personal, family, and community con-*
 17 *sequences of untreated addiction; and”.*

18 **SEC. 3. AMENDMENTS TO CONTROLLED SUBSTANCE MONI-**
 19 **TORING PROGRAM.**

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

22 *(1) in subsection (a)(1)—*

23 *(A) in the matter preceding subparagraph*
 24 *(A), by inserting “, in consultation with the Ad-*
 25 *ministrator of the Substance Abuse and Mental*
 26 *Health Services Administration and Director of*

1 *the Centers for Disease Control and Prevention,”*
 2 *after “the Secretary”;*

3 *(B) in subparagraph (A), by striking “or”;*

4 *(C) in subparagraph (B), by striking the*
 5 *period at the end and inserting “; or”; and*

6 *(D) by adding at the end the following:*

7 *“(C) to maintain an existing State-con-*
 8 *trolled substance monitoring program.”;*

9 *(2) by amending subsection (b) to read as fol-*
 10 *lows:*

11 *“(b) MINIMUM REQUIREMENTS.—The Secretary shall*
 12 *maintain and, as appropriate, supplement or revise (after*
 13 *publishing proposed additions and revisions in the Federal*
 14 *Register and receiving public comments thereon) minimum*
 15 *requirements for criteria to be used by States for purposes*
 16 *of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).”;*

17 *(3) in subsection (c)—*

18 *(A) in paragraph (1)(B)—*

19 *(i) in the matter preceding clause (i),*
 20 *by striking “(a)(1)(B)” and inserting*
 21 *“(a)(1)(B) or (a)(1)(C)”;*

22 *(ii) in clause (i), by striking “program*
 23 *to be improved” and inserting “program to*
 24 *be improved or maintained”;*

1 (iii) by redesignating clauses (iii) and
2 (iv) as clauses (iv) and (v), respectively;

3 (iv) by inserting after clause (ii), the
4 following:

5 “(iii) a plan to apply the latest ad-
6 vances in health information technology, to
7 the extent practicable, in order to incor-
8 porate prescription drug monitoring pro-
9 gram data directly into the workflow of pre-
10 scribers and dispensers to ensure timely ac-
11 cess to patients’ controlled prescription drug
12 history;”;

13 (v) in clause (iv) (as so redesign-
14 ated)—

15 (I) by inserting before the semi-
16 colon the following: “and at least one
17 health information technology system
18 such as electronic health records, health
19 information exchanges, and e-pre-
20 scribing systems”; and

21 (II) by striking “and” after the
22 semicolon;

23 (vi) in clause (v) (as so redesign-
24 ated)—

1 (I) by striking “public health”
 2 and inserting “public health or safety”;
 3 and

4 (II) by striking the period and in-
 5 serting “; and”; and

6 (vii) by adding at the end the fol-
 7 lowing:

8 “(vi) information, where applicable, on
 9 how the controlled substance monitoring
 10 program jointly works with the applicant’s
 11 respective State substance abuse agency to
 12 ensure information collected and main-
 13 tained by the controlled substance moni-
 14 toring program is used to inform the provi-
 15 sion of clinically appropriate substance use
 16 disorder services to individuals in need.”;

17 (B) in paragraph (3)—

18 (i) by striking “If a State that sub-
 19 mits” and inserting the following:

20 “(A) IN GENERAL.—If a State that sub-
 21 mits”;

22 (ii) by inserting before the period at
 23 the end “and include timelines for full im-
 24 plementation of such interoperability. The
 25 State shall also describe the manner in

1 *which it will achieve interoperability be-*
 2 *tween its monitoring program and health*
 3 *information technology systems, as allow-*
 4 *able under State law, and include timelines*
 5 *for the implementation of such interoper-*
 6 *ability”;* and

7 *(iii) by adding at the end the fol-*
 8 *lowing:*

9 “(B) *MONITORING OF EFFORTS.*—*The Sec-*
 10 *retary shall monitor State efforts to achieve*
 11 *interoperability, as described in subparagraph*
 12 *(A).”;* and

13 *(C) in paragraph (5)—*

14 *(i) by striking “implement or im-*
 15 *prove” and inserting “establish, improve, or*
 16 *maintain”;* and

17 *(ii) by adding at the end the following:*
 18 *“The Secretary shall redistribute any funds*
 19 *that are so returned among the remaining*
 20 *grantees under this section in accordance*
 21 *with the formula described in subsection*
 22 *(a)(2)(B).”;*

23 *(4) in subsection (d)—*

24 *(A) in the matter preceding paragraph*
 25 *(1)—*

1 (i) by striking “In implementing or
 2 improving” and all that follows through
 3 “(a)(1)(B)” and inserting “In establishing,
 4 improving, or maintaining a controlled
 5 substance monitoring program under this
 6 section, a State shall comply, or with re-
 7 spect to a State that applies for a grant
 8 under subparagraph (B) or (C) of sub-
 9 section (a)(1)”; and

10 (ii) by striking “public health” and in-
 11 serting “public health or safety”; and
 12 (B) by adding at the end the following:

13 “(5) The State shall report on interoperability
 14 with the controlled substance monitoring program of
 15 Federal agencies, where appropriate, interoperability
 16 with health information technology systems such as
 17 electronic health records, health information ex-
 18 changes, and e-prescribing, where appropriate, and
 19 whether or not the State provides automatic, up-to-
 20 date, or daily information about a patient when a
 21 practitioner (or the designee of a practitioner, where
 22 permitted) requests information about such patient.”;

23 (5) in subsections (e), (f)(1), and (g), by striking
 24 “implementing or improving” each place it appears

1 *and inserting “establishing, improving, or maintain-*
 2 *ing”;*

3 *(6) in subsection (f)—*

4 *(A) in paragraph (1)—*

5 *(i) in subparagraph (B), by striking*
 6 *“misuse of a schedule II, III, or IV sub-*
 7 *stance” and inserting “misuse of a con-*
 8 *trolled substance”; and*

9 *(ii) in subparagraph (D)—*

10 *(I) by inserting “a State sub-*
 11 *stance abuse agency,” after “State*
 12 *health department,”; and*

13 *(II) by striking “such department,*
 14 *program, or administration” each*
 15 *place it appears and inserting “such*
 16 *department, program, agency, or ad-*
 17 *ministration” in each such place; and*

18 *(B) by adding at the end the following:*

19 *“(3) EVALUATION AND REPORTING.—Subject to*
 20 *subsection (g), a State receiving a grant under sub-*
 21 *section (a) shall provide the Secretary with aggregate*
 22 *data to enable the Secretary—*

23 *“(A) to evaluate the success of the State’s*
 24 *program in achieving its purposes; or*

1 “(B) to prepare and submit the report to
2 Congress required by subsection (k)(2).

3 “(4) *RESEARCH BY OTHER ENTITIES*.—A depart-
4 ment, program, agency, or administration receiving
5 nonidentifiable information under paragraph (1)(D)
6 may make such information available to other entities
7 for research purposes.”;

8 (7) by striking subsection (k);

9 (8) by redesignating subsections (h) through (j)
10 as subsections (i) through (k), respectively;

11 (9) in subsections (c)(1)(A)(iv) and (d)(4), by
12 striking “subsection (h)” each place it appears and
13 inserting “subsection (i)”;

14 (10) by inserting after subsection (g) the fol-
15 lowing:

16 “(h) *EDUCATION AND ACCESS TO THE MONITORING*
17 *SYSTEM*.—A State receiving a grant under subsection (a)
18 shall take steps to—

19 “(1) facilitate prescriber and dispenser use of the
20 State’s controlled substance monitoring system, to the
21 extent practicable; and

22 “(2) educate prescribers and dispensers on the
23 benefits of the system.”;

24 (11) in subsection (k)(2)(A), as so redesignated—

1 (A) in clause (ii), by striking “or affected”
 2 and inserting “, established or strengthened ini-
 3 tiatives to ensure linkages to substance use dis-
 4 order services, or affected”; and

5 (B) in clause (iii), by striking “including
 6 an assessment” and inserting “and between con-
 7 trolled substance monitoring programs and
 8 health information technology systems, including
 9 an assessment”;

10 (12) in subsection (l)(1), by striking “establis-
 11 ment, implementation, or improvement” and insert-
 12 ing “establishment, improvement, or maintenance”;

13 (13) in subsection (m)(8), by striking “and the
 14 District of Columbia” and inserting “, the District of
 15 Columbia, and any commonwealth or territory of the
 16 United States”; and

17 (14) by amending subsection (n) to read as fol-
 18 lows:

19 “(n) *AUTHORIZATION OF APPROPRIATIONS.—To carry*
 20 *out this section, there are authorized to be appropriated*
 21 *such sums as may be necessary for each of fiscal years 2017*
 22 *through 2021.”.*

Calendar No. 440

114TH CONGRESS
2^D Session

S. 480

A BILL

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act.

APRIL 27, 2016

Reported with an amendment