

Calendar No. 46

115TH CONGRESS
1ST SESSION

S. 916

To amend the Controlled Substances Act with regard to the provision of emergency medical services.

IN THE SENATE OF THE UNITED STATES

APRIL 24, 2017

Mr. CASSIDY (for himself, Mr. BENNET, Mr. BLUNT, Mr. FRANKEN, Mr. ALEXANDER, Ms. MURKOWSKI, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

MAY 1, 2017

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 the Controlled Substances Act with regard to the provision of emergency medical services.

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 “Protecting Patient Ac-
5 cess to Emergency Medications Act of 2017”.

1 **SEC. 2. EMERGENCY MEDICAL SERVICES.**

2 Section 303 of the Controlled Substances Act (21
3 U.S.C. 823) is amended—

4 (1) by redesignating subsection (j) as sub-
5 section (k); and

6 (2) by inserting after subsection (i) the fol-
7 lowing:

8 “(j) **EMERGENCY MEDICAL SERVICES THAT ADMIN-**
9 **ISTER CONTROLLED SUBSTANCES.—**

10 “(1) **REGISTRATION.—**For the purpose of ena-
11 bling emergency medical services professionals to ad-
12 minister controlled substances in schedule II, III,
13 IV, or V to ultimate users receiving emergency med-
14 ical services in accordance with the requirements of
15 this subsection, the Attorney General—

16 “(A) shall register an emergency medical
17 services agency if the agency submits an appli-
18 cation demonstrating it is authorized to conduct
19 such activity under the laws of each State in
20 which the agency practices; and

21 “(B) may deny an application for such reg-
22 istration if the Attorney General determines
23 that the issuance of such registration would be
24 inconsistent with the requirements of this sub-
25 section or the public interest based on the fac-
26 tors listed in subsection (f).

1 “(2) OPTION FOR SINGLE REGISTRATION.—In
2 registering an emergency medical services agency
3 pursuant to paragraph (1), the Attorney General
4 shall allow such agency the option of a single reg-
5 istration in each State where the agency administers
6 controlled substances in lieu of requiring a separate
7 registration for each location of the emergency med-
8 ical services agency.

9 “(3) HOSPITAL-BASED AGENCY.—If a hospital-
10 based emergency medical services agency is reg-
11 istered under subsection (f), the agency may use the
12 registration of the hospital to administer controlled
13 substances in accordance with this subsection with-
14 out being registered under this subsection.

15 “(4) ADMINISTRATION OUTSIDE PHYSICAL
16 PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING
17 MEDICAL PROFESSIONAL.—Emergency medical serv-
18 ices professionals of a registered emergency medical
19 services agency may administer controlled sub-
20 stances in schedule II, III, IV, or V outside the
21 physical presence of a medical director or author-
22 izing medical professional in the course of providing
23 emergency medical services if the administration
24 is—

1 “(A) authorized by the law of the State in
2 which it occurs; and

3 “(B) pursuant to—

4 “(i) a standing order that is issued
5 and adopted by one or more medical direc-
6 tors of the agency, including any such
7 order that may be developed by a specific
8 State authority; or

9 “(ii) a verbal order that is—

10 “(I) issued in accordance with a
11 policy of the agency; and

12 “(II) provided by a medical direc-
13 tor or authorizing medical professional
14 in response to a request by the emer-
15 gency medical services professional
16 with respect to a specific patient—

17 “(aa) in the case of a mass
18 casualty incident; or

19 “(bb) to ensure the proper
20 care and treatment of a specific
21 patient.

22 “(5) DELIVERY.—A registered emergency med-
23 ical services agency may deliver controlled sub-
24 stances from a registered location of the agency to
25 an unregistered location of the agency only if—

1 “(A) the agency designates the unregis-
2 tered location for such delivery; and

3 “(B) notifies the Attorney General at least
4 30 days prior to first delivering controlled sub-
5 stances to the unregistered location.

6 “(6) STORAGE.—A registered emergency med-
7 ical services agency may store controlled sub-
8 stances—

9 “(A) at a registered location of the agency;

10 “(B) at any designated location of the
11 agency or in an emergency services vehicle situ-
12 ated at a registered or designated location of
13 the agency; or

14 “(C) in an emergency medical services ve-
15 hicle used by the agency that is—

16 “(i) traveling from, or returning to, a
17 registered or designated location of the
18 agency in the course of responding to an
19 emergency; or

20 “(ii) otherwise actively in use by the
21 agency under circumstances that provide
22 for security of the controlled substances
23 consistent with the requirements estab-
24 lished by regulations of the Attorney Gen-
25 eral.

1 ~~“(7) NO TREATMENT AS DISTRIBUTION.—The~~
2 delivery of controlled substances by a registered
3 emergency medical services agency pursuant to this
4 subsection shall not be treated as distribution for
5 purposes of section 308.

6 ~~“(8) RESTOCKING OF EMERGENCY MEDICAL~~
7 SERVICES VEHICLES AT A HOSPITAL.—Notwith-
8 standing paragraph (13)(J), a registered emergency
9 medical services agency may receive controlled sub-
10 stances from a hospital for purposes of restocking
11 an emergency medical services vehicle following an
12 emergency response, and without being subject to
13 the requirements of section 308, provided all of the
14 following conditions are satisfied:

15 ~~“(A) The registered or designated location~~
16 of the agency where the vehicle is primarily sit-
17 uated maintains a record of such receipt in ac-
18 cordance with paragraph (9).

19 ~~“(B) The hospital maintains a record of~~
20 such delivery to the agency in accordance with
21 section 307.

22 ~~“(C) If the vehicle is primarily situated at~~
23 a designated location, such location notifies the
24 registered location of the agency within 72

1 hours of the vehicle receiving the controlled
2 substances.

3 ~~“(9) MAINTENANCE OF RECORDS.—~~

4 ~~“(A) IN GENERAL.—A registered emer-~~
5 ~~gency medical services agency shall maintain~~
6 ~~records in accordance with subsections (a) and~~
7 ~~(b) of section 307 of all controlled substances~~
8 ~~that are received, administered, or otherwise~~
9 ~~disposed of pursuant to the agency’s registra-~~
10 ~~tion, without regard to subsection 307(c)(1)(B).~~

11 ~~“(B) REQUIREMENTS.—Such records—~~

12 ~~“(i) shall include records of deliveries~~
13 ~~of controlled substances between all loca-~~
14 ~~tions of the agency; and~~

15 ~~“(ii) shall be maintained, whether~~
16 ~~electronically or otherwise, at each reg-~~
17 ~~istered and designated location of the~~
18 ~~agency where the controlled substances in-~~
19 ~~volved are received, administered, or other-~~
20 ~~wise disposed of.~~

21 ~~“(10) OTHER REQUIREMENTS.—A registered~~
22 ~~emergency medical services agency, under the super-~~
23 ~~vision of a medical director, shall be responsible for~~
24 ~~ensuring that—~~

1 “(A) all emergency medical services profes-
 2 sionals who administer controlled substances
 3 using the agency’s registration act in accord-
 4 ance with the requirements of this subsection;

5 “(B) the recordkeeping requirements of
 6 paragraph (9) are met with respect to a reg-
 7 istered location and each designated location of
 8 the agency;

9 “(C) the applicable physical security re-
 10 quirements established by regulation of the At-
 11 torney General are complied with wherever con-
 12 trolled substances are stored by the agency in
 13 accordance with paragraph (6); and

14 “(D) the agency maintains, at a registered
 15 location of the agency, a record of the standing
 16 orders issued or adopted in accordance with
 17 paragraph (9).

18 “(11) REGULATIONS.—The Attorney General
 19 may issue regulations—

20 “(A) specifying, with regard to delivery of
 21 controlled substances under paragraph (5)—

22 “(i) the types of locations that may be
 23 designated under such paragraph; and

1 “(ii) the manner in which a notifica-
 2 tion under paragraph (5)(B) must be
 3 made;

4 “(B) specifying, with regard to the storage
 5 of controlled substances under paragraph (6),
 6 the manner in which such substances must be
 7 stored at registered and designated locations;
 8 including in emergency medical service vehicles;
 9 and

10 “(C) addressing the ability of hospitals,
 11 emergency medical services agencies, registered
 12 locations, and designated locations to deliver
 13 controlled substances to each other in the event
 14 of—

15 “(i) shortages of such substances;

16 “(ii) a public health emergency; or

17 “(iii) a mass casualty event.

18 “(12) RULE OF CONSTRUCTION.—Nothing in
 19 this subsection shall be construed—

20 “(A) to limit the authority vested in the
 21 Attorney General by other provisions of this
 22 title to take measures to prevent diversion of
 23 controlled substances; or

1 “(B) to override the authority of any State
2 to regulate the provision of emergency medical
3 services consistent with this subsection.

4 “(13) DEFINITIONS.—In this section:

5 “(A) The term ‘authorizing medical profes-
6 sional’ means an emergency or other physician,
7 or another medical professional (including an
8 advanced practice registered nurse or physician
9 assistant) who is—

10 “(i) registered under this Act;

11 “(ii) acting within the scope of the
12 registration; and

13 “(iii) whose scope of practice under a
14 State license or certification includes the
15 ability to provide verbal orders.

16 “(B) The term ‘designated location’ means
17 a location designated by an emergency medical
18 services agency under paragraph (5).

19 “(C) The term ‘emergency medical serv-
20 ices’ means emergency medical response and
21 emergency mobile medical services provided out-
22 side of a fixed medical facility.

23 “(D) The term ‘emergency medical services
24 agency’ means an organization providing emer-

1 gency medical services, including such an orga-
2 nization that—

3 “(i) is governmental (including fire-
4 based and hospital-based agencies), non-
5 governmental (including hospital-based
6 agencies), private, or volunteer-based;

7 “(ii) provides emergency medical serv-
8 ices by ground, air, or otherwise; and

9 “(iii) is authorized by the State in
10 which the organization is providing such
11 services to provide emergency medical care,
12 including the administering of controlled
13 substances, to members of the general pub-
14 lic on an emergency basis.

15 “(E) The term ‘emergency medical services
16 professional’ means a health care professional
17 (including a nurse, paramedic, or emergency
18 medical technician) licensed or certified by the
19 State in which the professional practices and
20 credentialed by a medical director of the respec-
21 tive emergency medical services agency to pro-
22 vide emergency medical services within the
23 scope of the professional’s State license or cer-
24 tification.

1 “(F) The term ‘emergency medical services
2 vehicle’ means an ambulance, fire apparatus,
3 supervisor truck, or other vehicle used by an
4 emergency medical services agency for the pur-
5 pose of providing or facilitating emergency med-
6 ical care and transport or transporting con-
7 trolled substances to and from the registered
8 and designated locations.

9 “(G) The term ‘hospital-based’ means,
10 with respect to an agency, owned or operated by
11 a hospital.

12 “(H) The term ‘medical director’ means a
13 physician who is registered under subsection (f)
14 and provides medical oversight for an emer-
15 gency medical services agency.

16 “(I) The term ‘medical oversight’ means
17 supervision of the provision of medical care by
18 an emergency medical services agency.

19 “(J) The term ‘registered location’ means
20 a location that appears on the certificate of reg-
21 istration issued to an emergency medical serv-
22 ices agency under this subsection or subsection
23 (f), which shall be where the agency receives
24 controlled substances from distributors.

1 “(K) The term ‘registered emergency med-
2 ical services agency’ means—

3 “(i) an emergency medical services
4 agency that is registered pursuant to this
5 subsection; or

6 “(ii) a hospital-based emergency med-
7 ical services agency that is covered by the
8 registration of the hospital under sub-
9 section (f).

10 “(L) The term ‘specific State authority’
11 means a governmental agency or other such au-
12 thority, including a regional oversight and co-
13 ordinating body, that, pursuant to State law or
14 regulation, develops clinical protocols regarding
15 the delivery of emergency medical services in
16 the geographic jurisdiction of such agency or
17 authority within the State that may be adopted
18 by medical directors.

19 “(M) The term ‘standing order’ means a
20 written medical protocol in which a medical di-
21 rector determines in advance the medical cri-
22 teria that must be met before administering
23 controlled substances to individuals in need of
24 emergency medical services.

“(N) The term ‘verbal order’ means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.”.

SEC. 3. DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO AN ADMINISTERING PRACTITIONER.

(a) IN GENERAL.—The Controlled Substance Act is amended by inserting after section 309 (21 U.S.C. 829) the following:

“SEC. 309A. DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO AN ADMINISTERING PRACTITIONER.

“Notwithstanding section 102(10), a pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of this Act and the regulations issued by the Attorney General under this Act, for the purpose of administering of the controlled substance by the practitioner if—

1 “(1) the controlled substance is delivered by the
2 pharmacy to the prescribing practitioner or the prac-
3 titioner administering the controlled substance, as
4 applicable, at the location listed on the practitioner’s
5 certificate of registration issued under this Act;

6 “(2)(A) in the case of administering of the con-
7 trolled substance for the purpose of maintenance or
8 detoxification treatment under section 303(g)(2)—

9 “(i) the practitioner who issued the pre-
10 scription is a qualifying practitioner authorized
11 under, and acting within the scope of that sec-
12 tion; and

13 “(ii) the controlled substance is to be ad-
14 ministered by injection, implantation, or use of
15 an intrathecal pump; or

16 “(B) in the case of administering of the con-
17 trolled substance for a purpose other than mainte-
18 nance or detoxification treatment, the controlled
19 substance is to be administered by a practitioner
20 through use of an intrathecal pump;

21 “(3) the pharmacy and the practitioner are au-
22 thorized to conduct the activities specified in this
23 section under the law of the State in which such ac-
24 tivities take place;

1 ~~“(4) the prescription is not issued to supply any~~
 2 ~~practitioner with a stock of controlled substances for~~
 3 ~~the purpose of general dispensing to patients;~~

4 ~~“(5) the controlled substance is to be adminis-~~
 5 ~~tered only to the patient named on the prescription~~
 6 ~~not later than 7 days, or longer if extended by the~~
 7 ~~Attorney General, after the date of receipt of the~~
 8 ~~controlled substance by the practitioner; and~~

9 ~~“(6) notwithstanding any exceptions under sec-~~
 10 ~~tion 307, the prescribing practitioner, and the prac-~~
 11 ~~titioner administering the controlled substance, as~~
 12 ~~applicable, maintain complete and accurate records~~
 13 ~~of all controlled substances delivered, received, ad-~~
 14 ~~ministered, or otherwise disposed of under this sec-~~
 15 ~~tion, including the persons to whom controlled sub-~~
 16 ~~stances were delivered and such other information as~~
 17 ~~may be required by regulations of the Attorney Gen-~~
 18 ~~eral.”.~~

19 ~~(b) TECHNICAL AND CONFORMING AMENDMENT.—~~
 20 ~~The table of contents for the Comprehensive Drug Abuse~~
 21 ~~Prevention and Control Act of 1970 is amended by insert-~~
 22 ~~ing after the item relating to section 309 the following:~~

~~“Sec. 309A. Delivery of a controlled substance by a pharmacy to an admin-~~
~~istering practitioner.”.~~

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Protecting Patient Ac-*
 3 *cess to Emergency Medications Act of 2017”.*

4 **SEC. 2. EMERGENCY MEDICAL SERVICES.**

5 *Section 303 of the Controlled Substances Act (21*
 6 *U.S.C. 823) is amended—*

7 *(1) by redesignating subsection (j) as subsection*
 8 *(k); and*

9 *(2) by inserting after subsection (i) the following:*

10 *“(j) EMERGENCY MEDICAL SERVICES THAT ADMIN-*
 11 *ISTER CONTROLLED SUBSTANCES.—*

12 *“(1) REGISTRATION.—For the purpose of ena-*
 13 *bling emergency medical services professionals to ad-*
 14 *minister controlled substances in schedule II, III, IV,*
 15 *or V to ultimate users receiving emergency medical*
 16 *services in accordance with the requirements of this*
 17 *subsection, the Attorney General—*

18 *“(A) shall register an emergency medical*
 19 *services agency if the agency submits an applica-*
 20 *tion demonstrating it is authorized to conduct*
 21 *such activity under the laws of each State in*
 22 *which the agency practices; and*

23 *“(B) may deny an application for such reg-*
 24 *istration if the Attorney General determines that*
 25 *the issuance of such registration would be incon-*
 26 *sistent with the requirements of this subsection*

1 *or the public interest based on the factors listed*
2 *in subsection (f).*

3 “(2) *OPTION FOR SINGLE REGISTRATION.*—*In*
4 *registering an emergency medical services agency pur-*
5 *suant to paragraph (1), the Attorney General shall*
6 *allow such agency the option of a single registration*
7 *in each State where the agency administers controlled*
8 *substances in lieu of requiring a separate registration*
9 *for each location of the emergency medical services*
10 *agency.*

11 “(3) *HOSPITAL-BASED AGENCY.*—*If a hospital-*
12 *based emergency medical services agency is registered*
13 *under subsection (f), the agency may use the registra-*
14 *tion of the hospital to administer controlled sub-*
15 *stances in accordance with this subsection without*
16 *being registered under this subsection.*

17 “(4) *ADMINISTRATION OUTSIDE PHYSICAL PRES-*
18 *ENCE OF MEDICAL DIRECTOR OR AUTHORIZING MED-*
19 *ICAL PROFESSIONAL.*—*Emergency medical services*
20 *professionals of a registered emergency medical serv-*
21 *ices agency may administer controlled substances in*
22 *schedule II, III, IV, or V outside the physical presence*
23 *of a medical director or authorizing medical profes-*
24 *sional in the course of providing emergency medical*
25 *services if the administration is—*

1 “(A) authorized by the law of the State in
2 which it occurs; and

3 “(B) pursuant to—

4 “(i) a standing order that is issued
5 and adopted by one or more medical direc-
6 tors of the agency, including any such order
7 that may be developed by a specific State
8 authority; or

9 “(ii) a verbal order that is—

10 “(I) issued in accordance with a
11 policy of the agency; and

12 “(II) provided by a medical direc-
13 tor or authorizing medical professional
14 in response to a request by the emer-
15 gency medical services professional
16 with respect to a specific patient—

17 “(aa) in the case of a mass
18 casualty incident; or

19 “(bb) to ensure the proper
20 care and treatment of a specific
21 patient.

22 “(5) DELIVERY.—A registered emergency medical
23 services agency may deliver controlled substances from
24 a registered location of the agency to an unregistered
25 location of the agency only if—

1 “(A) the agency designates the unregistered
2 location for such delivery; and

3 “(B) notifies the Attorney General at least
4 30 days prior to first delivering controlled sub-
5 stances to the unregistered location.

6 “(6) STORAGE.—A registered emergency medical
7 services agency may store controlled substances—

8 “(A) at a registered location of the agency;

9 “(B) at any designated location of the agen-
10 cy or in an emergency services vehicle situated at
11 a registered or designated location of the agency;
12 or

13 “(C) in an emergency medical services vehi-
14 cle used by the agency that is—

15 “(i) traveling from, or returning to, a
16 registered or designated location of the
17 agency in the course of responding to an
18 emergency; or

19 “(ii) otherwise actively in use by the
20 agency under circumstances that provide for
21 security of the controlled substances con-
22 sistent with the requirements established by
23 regulations of the Attorney General.

24 “(7) NO TREATMENT AS DISTRIBUTION.—The de-
25 livery of controlled substances by a registered emer-

1 *gency medical services agency pursuant to this sub-*
2 *section shall not be treated as distribution for pur-*
3 *poses of section 308.*

4 “(8) *RESTOCKING OF EMERGENCY MEDICAL*
5 *SERVICES VEHICLES AT A HOSPITAL.*—*Notwith-*
6 *standing paragraph (13)(J), a registered emergency*
7 *medical services agency may receive controlled sub-*
8 *stances from a hospital for purposes of restocking an*
9 *emergency medical services vehicle following an emer-*
10 *gency response, and without being subject to the re-*
11 *quirements of section 308, provided all of the fol-*
12 *lowing conditions are satisfied:*

13 “(A) *The registered or designated location of*
14 *the agency where the vehicle is primarily situ-*
15 *ated maintains a record of such receipt in ac-*
16 *cordance with paragraph (9).*

17 “(B) *The hospital maintains a record of*
18 *such delivery to the agency in accordance with*
19 *section 307.*

20 “(C) *If the vehicle is primarily situated at*
21 *a designated location, such location notifies the*
22 *registered location of the agency within 72 hours*
23 *of the vehicle receiving the controlled substances.*

24 “(9) *MAINTENANCE OF RECORDS.*—

1 “(A) *IN GENERAL.*—A registered emergency
 2 *medical services agency shall maintain records*
 3 *in accordance with subsections (a) and (b) of sec-*
 4 *tion 307 of all controlled substances that are re-*
 5 *ceived, administered, or otherwise disposed of*
 6 *pursuant to the agency’s registration, without re-*
 7 *gard to subsection 307(c)(1)(B).*

8 “(B) *REQUIREMENTS.*—Such records—

9 “(i) *shall include records of deliveries*
 10 *of controlled substances between all locations*
 11 *of the agency; and*

12 “(ii) *shall be maintained, whether elec-*
 13 *tronically or otherwise, at each registered*
 14 *and designated location of the agency where*
 15 *the controlled substances involved are re-*
 16 *ceived, administered, or otherwise disposed*
 17 *of.*

18 “(10) *OTHER REQUIREMENTS.*—A registered
 19 *emergency medical services agency, under the super-*
 20 *vision of a medical director, shall be responsible for*
 21 *ensuring that—*

22 “(A) *all emergency medical services profes-*
 23 *sionals who administer controlled substances*
 24 *using the agency’s registration act in accordance*
 25 *with the requirements of this subsection;*

1 “(B) the recordkeeping requirements of
 2 paragraph (9) are met with respect to a reg-
 3 istered location and each designated location of
 4 the agency;

5 “(C) the applicable physical security re-
 6 quirements established by regulation of the Attor-
 7 ney General are complied with wherever con-
 8 trolled substances are stored by the agency in ac-
 9 cordance with paragraph (6); and

10 “(D) the agency maintains, at a registered
 11 location of the agency, a record of the standing
 12 orders issued or adopted in accordance with
 13 paragraph (9).

14 “(11) REGULATIONS.—The Attorney General
 15 may issue regulations—

16 “(A) specifying, with regard to delivery of
 17 controlled substances under paragraph (5)—

18 “(i) the types of locations that may be
 19 designated under such paragraph; and

20 “(ii) the manner in which a notifica-
 21 tion under paragraph (5)(B) must be made;

22 “(B) specifying, with regard to the storage
 23 of controlled substances under paragraph (6), the
 24 manner in which such substances must be stored

1 *at registered and designated locations, including*
 2 *in emergency medical service vehicles; and*

3 “(C) *addressing the ability of hospitals,*
 4 *emergency medical services agencies, registered*
 5 *locations, and designated locations to deliver*
 6 *controlled substances to each other in the event*
 7 *of—*

8 “(i) *shortages of such substances;*

9 “(ii) *a public health emergency; or*

10 “(iii) *a mass casualty event.*

11 “(12) *RULE OF CONSTRUCTION.—Nothing in this*
 12 *subsection shall be construed—*

13 “(A) *to limit the authority vested in the At-*
 14 *torney General by other provisions of this title to*
 15 *take measures to prevent diversion of controlled*
 16 *substances; or*

17 “(B) *to override the authority of any State*
 18 *to regulate the provision of emergency medical*
 19 *services consistent with this subsection.*

20 “(13) *DEFINITIONS.—In this section:*

21 “(A) *The term ‘authorizing medical profes-*
 22 *sional’ means an emergency or other physician,*
 23 *or another medical professional (including an*
 24 *advanced practice registered nurse or physician*
 25 *assistant) who is—*

1 “(i) registered under this Act;

2 “(ii) acting within the scope of the reg-
3 istration; and

4 “(iii) whose scope of practice under a
5 State license or certification includes the
6 ability to provide verbal orders.

7 “(B) The term ‘designated location’ means a
8 location designated by an emergency medical
9 services agency under paragraph (5).

10 “(C) The term ‘emergency medical services’
11 means emergency medical response and emer-
12 gency mobile medical services provided outside of
13 a fixed medical facility.

14 “(D) The term ‘emergency medical services
15 agency’ means an organization providing emer-
16 gency medical services, including such an orga-
17 nization that—

18 “(i) is governmental (including fire-
19 based and hospital-based agencies), non-
20 governmental (including hospital-based
21 agencies), private, or volunteer-based;

22 “(ii) provides emergency medical serv-
23 ices by ground, air, or otherwise; and

24 “(iii) is authorized by the State in
25 which the organization is providing such

1 *services to provide emergency medical care,*
2 *including the administering of controlled*
3 *substances, to members of the general public*
4 *on an emergency basis.*

5 “(E) The term ‘emergency medical services
6 professional’ means a health care professional
7 (including a nurse, paramedic, or emergency
8 medical technician) licensed or certified by the
9 State in which the professional practices and
10 credentialed by a medical director of the respec-
11 tive emergency medical services agency to pro-
12 vide emergency medical services within the scope
13 of the professional’s State license or certification.

14 “(F) The term ‘emergency medical services
15 vehicle’ means an ambulance, fire apparatus, su-
16 pervisor truck, or other vehicle used by an emer-
17 gency medical services agency for the purpose of
18 providing or facilitating emergency medical care
19 and transport or transporting controlled sub-
20 stances to and from the registered and designated
21 locations.

22 “(G) The term ‘hospital-based’ means, with
23 respect to an agency, owned or operated by a
24 hospital.

1 “(H) The term ‘medical director’ means a
 2 physician who is registered under subsection (f)
 3 and provides medical oversight for an emergency
 4 medical services agency.

5 “(I) The term ‘medical oversight’ means su-
 6 pervision of the provision of medical care by an
 7 emergency medical services agency.

8 “(J) The term ‘registered location’ means a
 9 location that appears on the certificate of reg-
 10 istration issued to an emergency medical services
 11 agency under this subsection or subsection (f),
 12 which shall be where the agency receives con-
 13 trolled substances from distributors.

14 “(K) The term ‘registered emergency med-
 15 ical services agency’ means—

16 “(i) an emergency medical services
 17 agency that is registered pursuant to this
 18 subsection; or

19 “(ii) a hospital-based emergency med-
 20 ical services agency that is covered by the
 21 registration of the hospital under subsection
 22 (f).

23 “(L) The term ‘specific State authority’
 24 means a governmental agency or other such au-
 25 thority, including a regional oversight and co-

1 *ordinating body, that, pursuant to State law or*
2 *regulation, develops clinical protocols regarding*
3 *the delivery of emergency medical services in the*
4 *geographic jurisdiction of such agency or author-*
5 *ity within the State that may be adopted by*
6 *medical directors.*

7 *“(M) The term ‘standing order’ means a*
8 *written medical protocol in which a medical di-*
9 *rector determines in advance the medical criteria*
10 *that must be met before administering controlled*
11 *substances to individuals in need of emergency*
12 *medical services.*

13 *“(N) The term ‘verbal order’ means an oral*
14 *directive that is given through any method of*
15 *communication including by radio or telephone,*
16 *directly to an emergency medical services profes-*
17 *sional, to contemporaneously administer a con-*
18 *trolled substance to individuals in need of emer-*
19 *gency medical services outside the physical pres-*
20 *ence of the medical director or authorizing med-*
21 *ical professional.”.*

1 **SEC. 3. DELIVERY OF A CONTROLLED SUBSTANCE BY A**
 2 **PHARMACY TO AN ADMINISTERING PRACTI-**
 3 **TIONER.**

4 (a) *IN GENERAL.*—*The Controlled Substance Act is*
 5 *amended by inserting after section 309 (21. U.S.C. 829) the*
 6 *following:*

7 **“SEC. 309A. DELIVERY OF A CONTROLLED SUBSTANCE BY A**
 8 **PHARMACY TO AN ADMINISTERING PRACTI-**
 9 **TIONER.**

10 “(a) *IN GENERAL.*—*Notwithstanding section 102(10),*
 11 *a pharmacy may deliver a controlled substance to a practi-*
 12 *tioner in accordance with a prescription that meets the re-*
 13 *quirements of this Act and the regulations issued by the*
 14 *Attorney General under this Act, for the purpose of admin-*
 15 *istering of the controlled substance by the practitioner if—*

16 “(1) *the controlled substance is delivered by the*
 17 *pharmacy to the prescribing practitioner or the prac-*
 18 *titioner administering the controlled substance, as ap-*
 19 *plicable, at the location listed on the practitioner’s*
 20 *certificate of registration issued under this Act;*

21 “(2)(A) *in the case of administering of the con-*
 22 *trolled substance for the purpose of maintenance or*
 23 *detoxification treatment under section 303(g)(2)—*

24 “(i) *the practitioner who issued the pre-*
 25 *scription is a qualifying practitioner authorized*

1 *under, and acting within the scope of that sec-*
2 *tion; and*

3 *“(ii) the controlled substance is to be ad-*
4 *ministered by injection, implantation, or*
5 *through the use of an intrathecal pump; or*

6 *“(B) in the case of administering of the con-*
7 *trolled substance for a purpose other than mainte-*
8 *nance or detoxification treatment, the controlled sub-*
9 *stance is to be administered by a practitioner through*
10 *use of an intrathecal pump;*

11 *“(3) the pharmacy and the practitioner are au-*
12 *thorized to conduct the activities specified in this sec-*
13 *tion under the law of the State in which such activi-*
14 *ties take place;*

15 *“(4) the prescription is not issued to supply any*
16 *practitioner with a stock of controlled substances for*
17 *the purpose of general dispensing to patients;*

18 *“(5) except as provided in subsection (b), the*
19 *controlled substance is to be administered only to the*
20 *patient named on the prescription not later than 14*
21 *days after the date of receipt of the controlled sub-*
22 *stance by the practitioner; and*

23 *“(6) notwithstanding any exceptions under sec-*
24 *tion 307, the prescribing practitioner, and the practi-*
25 *tioner administering the controlled substance, as ap-*

1 *plicable, maintain complete and accurate records of*
 2 *all controlled substances delivered, received, adminis-*
 3 *tered, or otherwise disposed of under this section, in-*
 4 *cluding the persons to whom controlled substances*
 5 *were delivered and such other information as may be*
 6 *required by regulations of the Attorney General.*

7 “(b) *MODIFICATION OF NUMBER OF DAYS BEFORE*
 8 *WHICH CONTROLLED SUBSTANCE SHALL BE ADMINIS-*
 9 *TERED.—*

10 “(1) *INITIAL 2-YEAR PERIOD.—During the 2-*
 11 *year period beginning on the date of enactment of this*
 12 *section, the Attorney General, in coordination with*
 13 *the Secretary, may reduce the number of days de-*
 14 *scribed in subsection (a)(5) if the Attorney General*
 15 *determines that such reduction will—*

16 “(A) *reduce the risk of diversion; or*

17 “(B) *protect the public health.*

18 “(2) *MODIFICATIONS AFTER SUBMISSION OF RE-*
 19 *PORT.—After the date on which the report described*
 20 *in subsection (c) is submitted, the Attorney General,*
 21 *in coordination with the Secretary, may modify the*
 22 *number of days described in subsection (a)(5).*

23 “(3) *MINIMUM NUMBER OF DAYS.—Any modi-*
 24 *fication under this subsection shall be for a period of*
 25 *not less than 7 days.*

1 “(c) *STUDY AND REPORT.*—Not later than 2 years
 2 after the date of enactment of this section, the Comptroller
 3 General of the United States shall conduct a study and sub-
 4 mit to Congress a report on access to and potential diver-
 5 sion of controlled substances administered by injection, im-
 6 plantation, or through the use of an intrathecal pump.”.

7 (b) *TECHNICAL AND CONFORMING AMENDMENT.*—The
 8 table of contents for the Comprehensive Drug Abuse Preven-
 9 tion and Control Act of 1970 is amended by inserting after
 10 the item relating to section 309 the following:

“Sec. 309A. *Delivery of a controlled substance by a pharmacy to an admin-
 istering practitioner.*”.

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115TH CONGRESS
1ST Session

S. 916

A BILL

To amend the Controlled Substances Act with regard to the provision of emergency medical services.

MAY 1, 2017

Reported with an amendment