

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

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”.

6 **SEC. 2. EMERGENCY MEDICAL SERVICES.**

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

9 (1) by redesignating subsection (j) as sub-
10 section (k); and

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

3 “(j) EMERGENCY MEDICAL SERVICES THAT ADMIN-
4 ISTER CONTROLLED SUBSTANCES.—

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

11 “(A) shall register an emergency medical
12 services agency if the agency submits an appli-
13 cation demonstrating it is authorized to conduct
14 such activity under the laws of each State in
15 which the agency practices; and

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

22 “(2) OPTION FOR SINGLE REGISTRATION.—In
23 registering an emergency medical services agency
24 pursuant to paragraph (1), the Attorney General
25 shall allow such agency the option of a single reg-

1 istration in each State where the agency administers
2 controlled substances in lieu of requiring a separate
3 registration for each location of the emergency med-
4 ical services agency.

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

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

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

23 “(B) pursuant to—

24 “(i) a standing order that is issued
25 and adopted by one or more medical direc-

1 tors of the agency, including any such
2 order that may be developed by a specific
3 State authority; or

4 “(ii) a verbal order that is—

5 “(I) issued in accordance with a
6 policy of the agency; and

7 “(II) provided by a medical direc-
8 tor or authorizing medical professional
9 in response to a request by the emer-
10 gency medical services professional
11 with respect to a specific patient—

12 “(aa) in the case of a mass
13 casualty incident; or

14 “(bb) to ensure the proper
15 care and treatment of a specific
16 patient.

17 “(5) DELIVERY.—A registered emergency med-
18 ical services agency may deliver controlled sub-
19 stances from a registered location of the agency to
20 an unregistered location of the agency only if—

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

23 “(B) notifies the Attorney General at least
24 30 days prior to first delivering controlled sub-
25 stances to the unregistered location.

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

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

5 “(B) at any designated location of the
6 agency or in an emergency services vehicle situ-
7 ated at a registered or designated location of
8 the agency; or

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

11 “(i) traveling from, or returning to, a
12 registered or designated location of the
13 agency in the course of responding to an
14 emergency; or

15 “(ii) otherwise actively in use by the
16 agency under circumstances that provide
17 for security of the controlled substances
18 consistent with the requirements estab-
19 lished by regulations of the Attorney Gen-
20 eral.

21 “(7) NO TREATMENT AS DISTRIBUTION.—The
22 delivery of controlled substances by a registered
23 emergency medical services agency pursuant to this
24 subsection shall not be treated as distribution for
25 purposes of section 308.

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

10 “(A) The registered or designated location
11 of the agency where the vehicle is primarily sit-
12 uated maintains a record of such receipt in ac-
13 cordance with paragraph (9).

14 “(B) The hospital maintains a record of
15 such delivery to the agency in accordance with
16 section 307.

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

22 “(9) MAINTENANCE OF RECORDS.—

23 “(A) IN GENERAL.—A registered emer-
24 gency medical services agency shall maintain
25 records in accordance with subsections (a) and

1 (b) of section 307 of all controlled substances
2 that are received, administered, or otherwise
3 disposed of pursuant to the agency's registra-
4 tion, without regard to subsection 307(c)(1)(B).

5 “(B) REQUIREMENTS.—Such records—

6 “(i) shall include records of deliveries
7 of controlled substances between all loca-
8 tions of the agency; and

9 “(ii) shall be maintained, whether
10 electronically or otherwise, at each reg-
11 istered and designated location of the
12 agency where the controlled substances in-
13 volved are received, administered, or other-
14 wise disposed of.

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

19 “(A) all emergency medical services profes-
20 sionals who administer controlled substances
21 using the agency's registration act in accord-
22 ance with the requirements of this subsection;

23 “(B) the recordkeeping requirements of
24 paragraph (9) are met with respect to a reg-

1 istered location and each designated location of
2 the agency;

3 “(C) the applicable physical security re-
4 quirements established by regulation of the At-
5 torney General are complied with wherever con-
6 trolled substances are stored by the agency in
7 accordance with paragraph (6); and

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

12 “(11) REGULATIONS.—The Attorney General
13 may issue regulations—

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

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

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

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

1 including in emergency medical service vehicles;
2 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
12 this subsection shall be construed—

13 “(A) to limit the authority vested in the
14 Attorney General by other provisions of this
15 title to take measures to prevent diversion of
16 controlled 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
3 registration; 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
8 a location designated by an emergency medical
9 services agency under paragraph (5).

10 “(C) The term ‘emergency medical serv-
11 ices’ means emergency medical response and
12 emergency mobile medical services provided out-
13 side of 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 pub-
4 lic 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
13 scope of the professional’s State license or cer-
14 tification.

15 “(F) The term ‘emergency medical services
16 vehicle’ means an ambulance, fire apparatus,
17 supervisor truck, or other vehicle used by an
18 emergency medical services agency for the pur-
19 pose of providing or facilitating emergency med-
20 ical care and transport or transporting con-
21 trolled substances to and from the registered
22 and designated locations.

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

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

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

8 “(J) The term ‘registered location’ means
9 a location that appears on the certificate of reg-
10 istration issued to an emergency medical serv-
11 ices agency under this subsection or subsection
12 (f), which shall be where the agency receives
13 controlled 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 sub-
22 section (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
4 the geographic jurisdiction of such agency or
5 authority within the State that may be adopted
6 by 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 cri-
10 teria that must be met before administering
11 controlled substances to individuals in need of
12 emergency medical services.

13 “(N) The term ‘verbal order’ means an
14 oral directive that is given through any method
15 of communication including by radio or tele-
16 phone, directly to an emergency medical serv-
17 ices professional, to contemporaneously admin-
18 ister a controlled substance to individuals in
19 need of emergency medical services outside the
20 physical presence of the medical director or au-
21 thorizing medical 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)
6 the following:

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

10 “Notwithstanding section 102(10), a pharmacy may
11 deliver a controlled substance to a practitioner in accord-
12 ance with a prescription that meets the requirements of
13 this Act and the regulations issued by the Attorney Gen-
14 eral under this Act, for the purpose of administering of
15 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
19 applicable, 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 use of
5 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
9 substance is to be administered by a practitioner
10 through use of an intrathecal pump;

11 “(3) the pharmacy and the practitioner are au-
12 thorized to conduct the activities specified in this
13 section under the law of the State in which such ac-
14 tivities 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) the controlled substance is to be adminis-
19 tered only to the patient named on the prescription
20 not later than 7 days, or longer if extended by the
21 Attorney General, after the date of receipt of the
22 controlled substance by the practitioner; and

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

1 applicable, maintain complete and accurate records
2 of all controlled substances delivered, received, ad-
3 ministered, or otherwise disposed of under this sec-
4 tion, including the persons to whom controlled sub-
5 stances were delivered and such other information as
6 may be required by regulations of the Attorney Gen-
7 eral.”.

8 (b) TECHNICAL AND CONFORMING AMENDMENT.—
9 The table of contents for the Comprehensive Drug Abuse
10 Prevention and Control Act of 1970 is amended by insert-
11 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.”.

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