

## Calendar No. 46

115TH CONGRESS  
1ST SESSION

# S. 916

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

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### 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]

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## 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.*”.





**Calendar No. 46**

115<sup>TH</sup> CONGRESS  
1<sup>ST</sup> 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