

Union Calendar No. 628

114TH CONGRESS
2D SESSION

H. R. 4365

[Report No. 114–804, Part I]

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 12, 2016

Mr. HUDSON (for himself, Mr. BUTTERFIELD, Mr. COHEN, Mr. FARENTHOLD, Mr. HECK of Nevada, Mr. RUIZ, and Mr. WESTERMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

NOVEMBER 14, 2016

Additional sponsors: Mr. BLUMENAUER, Ms. JENKINS of Kansas, Mr. PETERSON, Mr. FITZPATRICK, Mr. HARRIS, Mr. SCHRADER, Mr. DAVID SCOTT of Georgia, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mr. ASHFORD, Mr. BURGESS, Mr. LONG, Mrs. BROOKS of Indiana, Mr. KIND, Mr. CARTWRIGHT, Mr. BILIRAKIS, Mr. SMITH of Texas, Mr. POCAN, Mr. SENSENBRENNER, Mr. TIPTON, Mr. YOUNG of Alaska, Mr. ZINKE, Ms. GABBARD, Mr. BRENDAN F. BOYLE of Pennsylvania, Mr. WALDEN, Mr. WESTMORELAND, Mr. DIAZ-BALART, Ms. ESHOO, Mr. LANGEVIN, Mr. COLLINS of New York, Mr. ABRAHAM, Mr. WALZ, Mr. CRAMER, Mr. CLAWSON of Florida, Ms. FRANKEL of Florida, Mr. NUGENT, Mr. DUNCAN of Tennessee, Mr. GRAVES of Missouri, Mr. YODER, Mr. LUETKEMEYER, Mr. DESJARLAIS, Mr. MULLIN, Mr. GARRETT, Mr. ROE of Tennessee, Mr. BLUM, Mr. CULBERSON, Mr. DEFazio, Mr. BOUSTANY, Ms. PINGREE, Mrs. BLACKBURN, Mr. FLEMING, Ms. MOORE, Mr. WILLIAMS, Mrs. KIRKPATRICK, Mr. HUELSKAMP, Mr. ALLEN, Mr. LUCAS, Mr. YOUNG of Iowa, Mr. POMPEO, Mr. SMITH of Washington, Mr. EMMER of Minnesota, Ms. BONAMICI, Mr. COSTELLO of Pennsylvania, Mr. ROUZER, Mr. JOYCE, Mr. GRAVES of Louisiana, Mr. WENSTRUP, Mr. BUCSHON, Mr. GRAVES of Georgia, Ms. SCHAKOWSKY,

Mr. JOLLY, Mr. VAN HOLLEN, Mr. BEYER, Mr. RIGELL, Mr. BROOKS of Alabama, Mr. MARCHANT, Mr. CONYERS, Mr. BARR, Mr. LANCE, Mr. ROSKAM, Mrs. McMORRIS RODGERS, Mr. CARTER of Texas, Mr. FORBES, Mrs. WAGNER, Mr. TED LIEU of California, Mr. CUMMINGS, Mrs. WALORSKI, Ms. DELBENE, Mr. WALBERG, Mr. MCCAUL, Mr. KILMER, Ms. BROWNLEY of California, Mr. DOLD, Mr. DONOVAN, Mr. WELCH, Mr. GUINTA, Mr. RICHMOND, Ms. GRANGER, Mr. PITTENGER, Mr. ELLISON, Ms. HERRERA BEUTLER, Mr. RENACCI, Mr. LABRADOR, Mr. ROGERS of Kentucky, Mr. PAULSEN, Mr. BABIN, Mr. STIVERS, Mr. SMITH of Missouri, Ms. CASTOR of Florida, Mr. BISHOP of Michigan, Ms. GRAHAM, Mr. GOSAR, Mr. MCHENRY, Mr. ROTHFUS, Mr. DUNCAN of South Carolina, Mrs. BEATTY, Mr. GUTHRIE, Mrs. NOEM, Mr. BRADY of Pennsylvania, Ms. HAHN, Mrs. ELLMERS of North Carolina, Mr. STEWART, Mr. DENT, Mrs. BUSTOS, Mr. COURTNEY, Mr. LIPINSKI, Miss RICE of New York, Mr. SCHWEIKERT, and Ms. MCSALLY

NOVEMBER 14, 2016

Reported from the Committee on Energy and Commerce with an amendment

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

NOVEMBER 14, 2016

The Committee on the Judiciary discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on January 12, 2016]

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 2016”.*

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

7 *Section 303 of the Controlled Substances Act (21*
 8 *U.S.C. 821 et seq.) is amended—*

9 *(1) by redesignating subsection (j) as subsection*
 10 *(k); and*

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

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

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

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

1 “(B) may deny an application for such reg-
2 istration if the Attorney General determines that
3 the issuance of such registration would be incon-
4 sistent with the requirements of this subsection
5 or the public interest based on the factors listed
6 in subsection (f).

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

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

21 “(4) *ADMINISTRATION OUTSIDE PHYSICAL PRES-*
22 *ENCE OF MEDICAL DIRECTOR OR AUTHORIZING MED-*
23 *ICAL PROFESSIONAL.*—Emergency medical services
24 professionals of a registrant emergency medical serv-
25 ices agency may administer controlled substances in

1 *schedule II, III, IV, or V outside the physical presence*
2 *of a medical director or authorizing medical profes-*
3 *sional in the course of providing emergency medical*
4 *services if the administration is—*

5 *“(A) authorized by the law of the State in*
6 *which it occurs; and*

7 *“(B) pursuant to—*

8 *“(i) a standing order that is—*

9 *“(I) issued and adopted by 1 or*
10 *more medical directors of the agency;*
11 *or*

12 *“(II) developed by a specific State*
13 *authority; or*

14 *“(ii) a verbal order that is—*

15 *“(I) issued in accordance with a*
16 *policy of the agency;*

17 *“(II) provided by an authorizing*
18 *medical professional in response to a*
19 *request by the emergency medical serv-*
20 *ices professional with respect to a spe-*
21 *cific patient;*

22 *“(III) in the case of a mass cas-*
23 *ualty incident; or*

24 *“(IV) to ensure the proper care*
25 *and treatment of a specific patient.*

1 “(5) *DELIVERY.*—A registrant emergency med-
2 ical services agency may deliver controlled substances
3 from a registered location of the agency to an unregis-
4 tered location of the agency only if—

5 “(A) the agency designates the unregistered
6 location for such delivery; and

7 “(B) notifies the Attorney General at least
8 30 days prior to first delivering controlled sub-
9 stances to the unregistered location.

10 “(6) *STORAGE.*—A registrant emergency medical
11 services agency may store controlled substances—

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

13 “(B) at any designated location of the agen-
14 cy or in an emergency services vehicle situated at
15 a registered or designated location of the agency;
16 or

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

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

23 “(ii) otherwise actively in use by the
24 agency.

1 “(7) *NO TREATMENT AS DISTRIBUTION.*—*The de-*
2 *livery of controlled substances by a registrant emer-*
3 *gency medical services agency pursuant to this sub-*
4 *section shall not be treated as distribution for pur-*
5 *poses of section 308.*

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

15 “(A) *The registered or designated location of*
16 *the agency where the vehicle is primarily situ-*
17 *ated 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 hours*
25 *of the vehicle receiving the controlled substances.*

1 “(9) *MAINTENANCE OF RECORDS.*—

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

9 “(B) *REQUIREMENTS.*—*Such records—*

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

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

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

23 “(A) *all emergency medical services profes-*
24 *sionals who administer controlled substances*

1 *using the agency’s registration act in accordance*
2 *with the requirements of this subsection;*

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

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

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

16 “(11) *REGULATIONS.—The Attorney General*
17 *may issue regulations—*

18 “(A) *specifying, with regard to delivery of*
19 *controlled substances under paragraph (5)—*

20 “(i) *the types of locations that may*
21 *designated under such paragraph; and*

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

24 “(B) *specifying, with regard to the storage*
25 *of controlled substances under paragraph (6), the*

1 manner in which such substances must be stored
2 at registered and designated locations, including
3 in emergency medical service vehicles; and

4 “(C) addressing the ability of hospitals, reg-
5 istered locations, and designated locations to de-
6 liver controlled substances to each other in the
7 event 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.

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

21 “(A) The term ‘designated location’ means a
22 location designated by an emergency medical
23 services agency under paragraph (5).

24 “(B) The term ‘emergency medical services’
25 means emergency medical response and emer-

1 *gency mobile medical services provided outside of*
2 *a fixed medical facility.*

3 “(C) *The term ‘emergency medical services*
4 *agency’ means an organization providing emer-*
5 *gency medical services, including such an orga-*
6 *nization that—*

7 “(i) *is governmental (including fire-*
8 *based and hospital-based agencies), non-*
9 *governmental (including hospital-based*
10 *agencies), private, or volunteer-based;*

11 “(ii) *provides emergency medical serv-*
12 *ices by ground, air, or otherwise; and*

13 “(iii) *is authorized by the State in*
14 *which the organization is providing such*
15 *services to provide emergency medical care,*
16 *including the administering of controlled*
17 *substances, to members of the general public*
18 *on an emergency basis.*

19 “(D) *The term ‘emergency medical services*
20 *professional’ means a health care professional*
21 *(including a nurse, paramedic, or emergency*
22 *medical technician) licensed or certified by the*
23 *State in which the professional practices and*
24 *credentialed by a medical director of the respec-*
25 *tive emergency medical services agency to pro-*

1 *vide emergency medical services within the scope*
2 *of the professional's State license or certification.*

3 “(E) The term ‘emergency medical services
4 vehicle’ means an ambulance, fire apparatus, su-
5 pervisor truck, or other vehicle owned or operated
6 by an emergency medical services agency for the
7 purpose of providing or facilitating emergency
8 medical care and transport or transporting con-
9 trolled substances to and from the registered and
10 designated locations.

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

14 “(G) The term ‘medical director’ means a
15 physician who is registered under subsection (f)
16 and provides medical oversight for an emergency
17 medical services agency.

18 “(H) The term ‘medical oversight’ means
19 supervision of the provision of medical care by
20 an emergency medical services agency.

21 “(I) The term ‘medical professional’ means
22 an emergency or other physician, or another
23 medical professional (including an advanced
24 practice registered nurse or physician assistant)
25 whose scope of practice under a State license or

1 *certification includes the ability to provide*
2 *verbal orders.*

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

9 “(K) *The term ‘registrant emergency med-*
10 *ical services agency’ means—*

11 “(i) *an emergency medical services*
12 *agency that is registered pursuant to this*
13 *subsection; or*

14 “(ii) *a hospital-based emergency med-*
15 *ical services agency that is covered by the*
16 *registration of the hospital under subsection*
17 *(f).*

18 “(L) *The term ‘specific State authority’*
19 *means a governmental agency or other such au-*
20 *thority, including a regional oversight and co-*
21 *ordinating body, that, pursuant to State law or*
22 *regulation, develops clinical protocols regarding*
23 *the delivery of emergency medical services in the*
24 *geographic jurisdiction of such agency or author-*

1 *ity within the State that may be adopted by*
2 *medical directors.*

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

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

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114TH CONGRESS
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