

**Suspend the Rules and Pass the Bill, H.R. 4365, with An Amendment**

**(The amendment strikes all after the enacting clause and inserts a new text)**

114<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4365

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

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## 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

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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 2016”.

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

2 Section 303 of the Controlled Substances Act (21  
3 U.S.C. 821 et seq.) 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 1 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;

12                         “(II) provided by an authorizing  
13                         medical professional in response to a  
14                         request by the emergency medical  
15                         services professional with respect to a  
16                         specific patient;

17                         “(III) in the case of a mass cas-  
18                         ualty incident; or

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

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

22           “(7) NO TREATMENT AS DISTRIBUTION.—The  
23           delivery of controlled substances by a registered  
24           emergency medical services agency pursuant to this

1 subsection shall not be treated as distribution for  
2 purposes of section 308.

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

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

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

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

24 “(9) MAINTENANCE OF RECORDS.—

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

8           “(B) REQUIREMENTS.—Such records—

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

12                   “(ii) shall be maintained, whether  
13                  electronically or otherwise, at each reg-  
14                  istered and designated location of the  
15                  agency where the controlled substances in-  
16                  volved are received, administered, or other-  
17                  wise disposed 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 accord-  
25                  ance 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 At-  
7 torney General are complied with wherever con-  
8 trolled substances are stored by the agency in  
9 accordance 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  
19 designated under such paragraph; and

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

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



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

4 “(C) addressing the ability of hospitals,  
5 registered locations, and designated locations to  
6 deliver controlled substances to each other in  
7 the 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  
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.

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

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

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

1 emergency mobile medical services provided out-  
2 side of 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 pub-  
18 lic 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  
2           scope of the professional's State license or cer-  
3           tification.

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

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

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

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

22          “(I) The term ‘medical professional’ means  
23          an emergency or other physician, or another  
24          medical professional (including an advanced  
25          practice registered nurse or physician assistant)

1           whose scope of practice under a State license or  
2           certification includes the ability to provide  
3           verbal orders.

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

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

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

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

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

1 authority within the State that may be adopted  
2 by 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 cri-  
6 teria that must be met before administering  
7 controlled substances to individuals in need of  
8 emergency medical services.

9 “(N) The term ‘verbal order’ means an  
10 oral directive that is given through any method  
11 of communication including by radio or tele-  
12 phone, directly to an emergency medical serv-  
13 ices professional, to contemporaneously admin-  
14 ister a controlled substance to individuals in  
15 need of emergency medical services outside the  
16 physical presence of the authorizing medical di-  
17 rector.”.