

## COMMITTEE PRINT

[SHOWING THE TEXT OF H.R. 4365 AS FORWARDED BY THE SUBCOMMITTEE  
ON HEALTH ON SEPTEMBER 13, 2016]

114TH CONGRESS  
2D 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 an emer-  
10          gency medical services agency is owned or operated  
11          by a hospital, and the agency is covered by the reg-  
12          istration of the hospital under subsection (f), the  
13          agency is deemed to have registered under this sub-  
14          section for purposes of this subsection.

15          “(4) ADMINISTRATION OUTSIDE PHYSICAL  
16          PRESENCE OF AUTHORIZING MEDICAL DIRECTOR.—  
17          Emergency medical services professionals of a reg-  
18          istrant emergency medical services agency may ad-  
19          minister controlled substances in schedule II, III,  
20          IV, or V outside the physical presence of the author-  
21          izing medical director in the course of providing  
22          emergency medical services pursuant to—

23                       “(A) a standing order issued or adopted by  
24                       one or more medical directors of such agency to

1 the extent such administering is authorized by  
2 the law of the State in which it occurs; or

3 “(B) a verbal order that is issued in ac-  
4 cordance with a policy of such agency and that  
5 is provided by a medical director—

6 “(i) in response to a request by the  
7 emergency medical services professional  
8 with respect to a specific patient;

9 “(ii) in the case of a mass casualty in-  
10 cident; or

11 “(iii) to ensure the proper care and  
12 treatment of a specific patient.

13 “(5) DELIVERY.—

14 “(A) IN GENERAL.—A registrant emer-  
15 gency medical services agency may deliver con-  
16 trolled substances from a registered location of  
17 the agency to an unregistered location of the  
18 agency only if—

19 “(i) the agency designates the unreg-  
20 istered location for such delivery; and

21 “(ii) notifies the Attorney General at  
22 least 30 days prior to delivering controlled  
23 substances to the unregistered location.

24 “(B) REGULATIONS.—The Attorney Gen-  
25 eral may issue regulations specifying—

1                   “(i) the types of locations that may be  
2                   so designated; and

3                   “(ii) the manner in which such notifi-  
4                   cation shall be made.

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

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

9                   “(B) at any location of the agency that is  
10                  designated under paragraph (5); or

11                  “(C) in an emergency medical services ve-  
12                  hicle used by the agency that is traveling from,  
13                  or returning to, such a registered or designated  
14                  location in the course of responding to emer-  
15                  gencies.

16                  “(7) NO TREATMENT AS DISTRIBUTION.—The  
17                  delivery of controlled substances by a registrant  
18                  emergency medical services agency pursuant to this  
19                  subsection shall not be treated as distribution for  
20                  purposes of section 308.

21                  “(8) MAINTENANCE OF RECORDS.—

22                  “(A) IN GENERAL.—A registrant emer-  
23                  gency medical services agency shall maintain  
24                  records in accordance with subsections (a) and  
25                  (b) of section 307 of all controlled substances

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

4 “(B) REQUIREMENTS.—Such records—

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

8 “(ii) shall be maintained at each loca-  
9 tion of the agency where the controlled  
10 substances involved are received, adminis-  
11 tered, or otherwise disposed of.

12 “(9) OTHER REQUIREMENTS.—A registrant  
13 emergency medical services agency, under the super-  
14 vision of a medical director, shall be responsible for  
15 ensuring that—

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

20 “(B) the recordkeeping requirements of  
21 paragraph (8) are met with respect to a reg-  
22 istered location of the agency and each location  
23 of the agency that is designated under para-  
24 graph (5);

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

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

10          “(10) DEFINITIONS.—In this section:

11           “(A) The term ‘emergency medical serv-  
12           ices’ means emergency medical response and  
13           emergency mobile medical services provided out-  
14           side of an immobile medical facility.

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

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

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

1           “(iii) is authorized by the State in  
2           which the organization is providing such  
3           services to provide emergency medical care,  
4           including the administering of controlled  
5           substances, to members of the general pub-  
6           lic on an emergency basis.

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

17          “(D) The term ‘hospital-based’ means,  
18          with respect to an agency, owned or operated by  
19          a hospital.

20          “(E) The term ‘medical director’ means—

21                 “(i) a physician who is registered  
22                 under subsection (f) and provides medical  
23                 oversight for an emergency medical serv-  
24                 ices agency; or



1           “(ii) another practitioner who is so  
2           registered and provides such oversight as  
3           authorized by the law of the State in which  
4           the agency operates.

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

8           “(G) 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          “(H) The term ‘registrant 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 that owns and oper-  
20               ates an emergency medical services agency  
21               that is registered pursuant to subsection  
22               (f).

23          “(I) The term ‘standing order’ means a  
24          written medical protocol in which a medical di-  
25          rector determines in advance the medical cri-

1           teria that must be met before administering  
2           controlled substances to individuals in need of  
3           emergency medical services.

4                   “(J) The term ‘verbal order’ means an oral  
5           directive that is given through any method of  
6           communication including by radio or telephone,  
7           directly to an emergency medical services pro-  
8           fessional, and to contemporaneously administer  
9           a controlled substance to a member of the gen-  
10          eral public in need of emergency medical serv-  
11          ices outside the physical presence of the author-  
12          izing medical director.

13                   “(11) RULE OF CONSTRUCTION.—Nothing in  
14          this section shall be construed—

15                   “(A) to limit the authority vested in the  
16          Attorney General by other provisions of this  
17          title to take measures to prevent diversion of  
18          controlled substances; or

19                   “(B) to override the authority of any State  
20          to regulate the provision of emergency medical  
21          services.”.