

114TH CONGRESS
2^D SESSION

H. R. 4365

IN THE SENATE OF THE UNITED STATES

NOVEMBER 15, 2016

Received

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Protecting Patient Ac-
3 cess to Emergency Medications Act of 2016”.

4 **SEC. 2. EMERGENCY MEDICAL SERVICES.**

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

7 (1) by redesignating subsection (j) as sub-
8 section (k); and

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

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

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

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

24 “(B) may deny an application for such reg-
25 istration if the Attorney General determines
26 that the issuance of such registration would be

1 inconsistent with the requirements of this sub-
2 section or the public interest based on the fac-
3 tors listed in subsection (f).

4 “(2) OPTION FOR SINGLE REGISTRATION.—In
5 registering an emergency medical services agency
6 pursuant to paragraph (1), the Attorney General
7 shall allow such agency the option of a single reg-
8 istration in each State where the agency administers
9 controlled substances in lieu of requiring a separate
10 registration for each location of the emergency med-
11 ical services agency.

12 “(3) HOSPITAL-BASED AGENCY.—If a hospital-
13 based emergency medical services agency is reg-
14 istered under subsection (f), the agency may use the
15 registration of the hospital to administer controlled
16 substances in accordance with this subsection with-
17 out being registered under this subsection.

18 “(4) ADMINISTRATION OUTSIDE PHYSICAL
19 PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING
20 MEDICAL PROFESSIONAL.—Emergency medical serv-
21 ices professionals of a registered emergency medical
22 services agency may administer controlled sub-
23 stances in schedule II, III, IV, or V outside the
24 physical presence of a medical director or author-
25 izing medical professional in the course of providing

1 emergency medical services if the administration
2 is—

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

5 “(B) pursuant to—

6 “(i) a standing order that is issued
7 and adopted by one or more medical direc-
8 tors of the agency, including any such
9 order that may be developed by a specific
10 State authority; or

11 “(ii) a verbal order that is—

12 “(I) issued in accordance with a
13 policy of the agency;

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

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

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

23 “(5) DELIVERY.—A registered emergency med-
24 ical services agency may deliver controlled sub-

1 stances from a registered location of the agency to
2 an unregistered location of the agency only if—

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

5 “(B) notifies the Attorney General at least
6 30 days prior to first delivering controlled sub-
7 stances to the unregistered location.

8 “(6) STORAGE.—A registered emergency med-
9 ical services agency may store controlled sub-
10 stances—

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

12 “(B) at any designated location of the
13 agency or in an emergency services vehicle situ-
14 ated at a registered or designated location of
15 the agency; or

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

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

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

24 “(7) NO TREATMENT AS DISTRIBUTION.—The
25 delivery of controlled substances by a registered

1 emergency medical services agency pursuant to this
2 subsection shall not be treated as distribution for
3 purposes 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
9 an emergency medical services vehicle following an
10 emergency response, and without being subject to
11 the requirements of section 308, provided all of the
12 following conditions are satisfied:

13 “(A) The registered or designated location
14 of the agency where the vehicle is primarily sit-
15 uated 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
23 hours of the vehicle receiving the controlled
24 substances.

25 “(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.”.

Passed the House of Representatives November 14,
2016.

Attest:

KAREN L. HAAS,

Clerk.