

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 4365
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

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—

1 “(A) shall register an emergency medical
2 services agency if the agency submits an appli-
3 cation demonstrating it is authorized to conduct
4 such activity under the laws of each State in
5 which the agency practices; and

6 “(B) may deny an application for such reg-
7 istration if the Attorney General determines
8 that the issuance of such registration would be
9 inconsistent with the requirements of this sub-
10 section or the public interest based on the fac-
11 tors listed in subsection (f).

12 “(2) OPTION FOR SINGLE REGISTRATION.—In
13 registering an emergency medical services agency
14 pursuant to paragraph (1), the Attorney General
15 shall allow such agency the option of a single reg-
16 istration in each State where the agency administers
17 controlled substances in lieu of requiring a separate
18 registration for each location of the emergency med-
19 ical services agency.

20 “(3) HOSPITAL-BASED AGENCY.—If a hospital-
21 based emergency medical services agency is reg-
22 istered under subsection (f), the agency may use the
23 registration of the hospital to administer controlled
24 substances in accordance with this subsection with-
25 out being registered under this subsection.

1 “(4) ADMINISTRATION OUTSIDE PHYSICAL
2 PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING
3 MEDICAL PROFESSIONAL.—Emergency medical serv-
4 ices professionals of a registrant emergency medical
5 services agency may administer controlled sub-
6 stances in schedule II, III, IV, or V outside the
7 physical presence of a medical director or author-
8 izing medical professional in the course of providing
9 emergency medical services if the administration
10 is—

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

13 “(B) pursuant to—

14 “(i) a standing order that is—

15 “(I) issued and adopted by 1 or
16 more medical directors of the agency;
17 or

18 “(II) developed by a specific
19 State authority; or

20 “(ii) a verbal order that is—

21 “(I) issued in accordance with a
22 policy of the agency;

23 “(II) provided by an authorizing
24 medical professional in response to a
25 request by the emergency medical

1 services professional with respect to a
2 specific patient;

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

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

7 “(5) DELIVERY.—A registrant emergency med-
8 ical services agency may deliver controlled sub-
9 stances from a registered location of the agency to
10 an unregistered location of the agency only if—

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

13 “(B) notifies the Attorney General at least
14 30 days prior to first delivering controlled sub-
15 stances to the unregistered location.

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

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

20 “(B) at any designated location of the
21 agency or in an emergency services vehicle situ-
22 ated at a registered or designated location of
23 the agency; or

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

1 “(i) traveling from, or returning to, a
2 registered or designated location of the
3 agency in the course of responding to an
4 emergency; or

5 “(ii) otherwise actively in use by the
6 agency.

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

12 “(8) RESTOCKING OF EMERGENCY MEDICAL
13 SERVICES VEHICLES AT A HOSPITAL.—Notwith-
14 standing paragraph (13)(J), a registrant emergency
15 medical services agency may receive controlled sub-
16 stances from a hospital for purposes of restocking
17 an emergency medical services vehicle following an
18 emergency response, and without being subject to
19 the requirements of section 308, provided all of the
20 following conditions are satisfied:

21 “(A) The registered or designated location
22 of the agency where the vehicle is primarily sit-
23 uated maintains a record of such receipt in ac-
24 cordance with paragraph (9).

1 “(B) The hospital maintains a record of
2 such delivery to the agency in accordance with
3 section 307.

4 “(C) If the vehicle is primarily situated at
5 a designated location, such location notifies the
6 registered location of the agency within 72
7 hours of the vehicle receiving the controlled
8 substances.

9 “(9) MAINTENANCE OF RECORDS.—

10 “(A) IN GENERAL.—A registrant emer-
11 gency medical services agency shall maintain
12 records in accordance with subsections (a) and
13 (b) of section 307 of all controlled substances
14 that are received, administered, or otherwise
15 disposed of pursuant to the agency’s registra-
16 tion, without regard to subsection 307(c)(1)(B).

17 “(B) REQUIREMENTS.—Such records—

18 “(i) shall include records of deliveries
19 of controlled substances between all loca-
20 tions of the agency; and

21 “(ii) shall be maintained, whether
22 electronically or otherwise, at each reg-
23 istered and designated location of the
24 agency where the controlled substances in-

1 volved are received, administered, or other-
2 wise disposed of.

3 “(10) OTHER REQUIREMENTS.—A registrant
4 emergency medical services agency, under the super-
5 vision of a medical director, shall be responsible for
6 ensuring that—

7 “(A) all emergency medical services profes-
8 sionals who administer controlled substances
9 using the agency’s registration act in accord-
10 ance with the requirements of this subsection;

11 “(B) the recordkeeping requirements of
12 paragraph (9) are met with respect to a reg-
13 istered location and each designated location of
14 the agency;

15 “(C) the applicable physical security re-
16 quirements established by regulation of the At-
17 torney General are complied with wherever con-
18 trolled substances are stored by the agency in
19 accordance with paragraph (6); and

20 “(D) the agency maintains, at a registered
21 location of the agency, a record of the standing
22 orders issued or adopted in accordance with
23 paragraph (9).

24 “(11) REGULATIONS.—The Attorney General
25 may issue regulations—

1 “(A) specifying, with regard to delivery of
2 controlled substances under paragraph (5)—

3 “(i) the types of locations that may
4 designated under such paragraph; and

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

8 “(B) specifying, with regard to the storage
9 of controlled substances under paragraph (6),
10 the manner in which such substances must be
11 stored at registered and designated locations,
12 including in emergency medical service vehicles;
13 and

14 “(C) addressing the ability of hospitals,
15 registered locations, and designated locations to
16 deliver controlled substances to each other in
17 the event of—

18 “(i) shortages of such substances;

19 “(ii) a public health emergency; or

20 “(iii) a mass casualty event.

21 “(12) RULE OF CONSTRUCTION.—Nothing in
22 this subsection shall be construed—

23 “(A) to limit the authority vested in the
24 Attorney General by other provisions of this

1 title to take measures to prevent diversion of
2 controlled substances; or

3 “(B) to override the authority of any State
4 to regulate the provision of emergency medical
5 services.

6 “(13) DEFINITIONS.—In this section:

7 “(A) The term ‘designated location’ means
8 a location designated by an emergency medical
9 services agency under paragraph (5).

10 “(B) The term ‘emergency medical serv-
11 ices’ means emergency medical response and
12 emergency mobile medical services provided out-
13 side of a fixed medical facility.

14 “(C) 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 pub-
4 lic on an emergency basis.

5 “(D) 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
13 scope of the professional’s State license or cer-
14 tification.

15 “(E) The term ‘emergency medical services
16 vehicle’ means an ambulance, fire apparatus,
17 supervisor truck, or other vehicle owned or op-
18 erated by an emergency medical services agency
19 for the purpose of providing or facilitating
20 emergency medical care and transport or trans-
21 porting controlled substances to and from the
22 registered and designated locations.

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

1 “(G) The term ‘medical director’ means a
2 physician who is registered under subsection (f)
3 and provides medical oversight for an emer-
4 gency medical services agency.

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

8 “(I) The term ‘medical professional’ means
9 an emergency or other physician, or another
10 medical professional (including an advanced
11 practice registered nurse or physician assistant)
12 whose scope of practice under a State license or
13 certification includes the ability to provide
14 verbal orders.

15 “(J) The term ‘registered location’ means
16 a location that appears on the certificate of reg-
17 istration issued to an emergency medical serv-
18 ices agency under this subsection or subsection
19 (f), which shall be where the agency receives
20 controlled substances from distributors.

21 “(K) The term ‘registrant emergency med-
22 ical services agency’ means—

23 “(i) an emergency medical services
24 agency that is registered pursuant to this
25 subsection; or

1 “(ii) a hospital-based emergency med-
2 ical services agency that is covered by the
3 registration of the hospital under sub-
4 section (f).

5 “(L) The term ‘specific State authority’
6 means a governmental agency or other such au-
7 thority, including a regional oversight and co-
8 ordinating body, that, pursuant to State law or
9 regulation, develops clinical protocols regarding
10 the delivery of emergency medical services in
11 the geographic jurisdiction of such agency or
12 authority within the State that may be adopted
13 by medical directors.

14 “(M) The term ‘standing order’ means a
15 written medical protocol in which a medical di-
16 rector determines in advance the medical cri-
17 teria that must be met before administering
18 controlled substances to individuals in need of
19 emergency medical services.

20 “(N) The term ‘verbal order’ means an
21 oral directive that is given through any method
22 of communication including by radio or tele-
23 phone, directly to an emergency medical serv-
24 ices professional, to contemporaneously admin-
25 ister a controlled substance to individuals in

1 need of emergency medical services outside the
2 physical presence of the authorizing medical di-
3 rector.”.

