

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

H. R. 304

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

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by Mr. CASSIDY (for himself, Mr. BEN-
NET, Mr. BLUNT, and Mr. FRANKEN)

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Protecting Patient Ac-
5 cess to Emergency Medications Act of 2017”.

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

7 Section 303 of the Controlled Substances Act (21
8 U.S.C. 823) is amended—

9 (1) by redesignating subsection (j) as sub-
10 section (k); and

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

3 “(j) EMERGENCY MEDICAL SERVICES THAT ADMIN-
4 ISTER CONTROLLED SUBSTANCES.—

5 “(1) REGISTRATION.—For the purpose of ena-
6 bling emergency medical services professionals to ad-
7 minister controlled substances in schedule II, III,
8 IV, or V to ultimate users receiving emergency med-
9 ical services in accordance with the requirements of
10 this subsection, the Attorney General—

11 “(A) shall register an emergency medical
12 services agency if the agency submits an appli-
13 cation demonstrating it is authorized to conduct
14 such activity under the laws of each State in
15 which the agency practices; and

16 “(B) may deny an application for such reg-
17 istration if the Attorney General determines
18 that the issuance of such registration would be
19 inconsistent with the requirements of this sub-
20 section or the public interest based on the fac-
21 tors listed in subsection (f).

22 “(2) OPTION FOR SINGLE REGISTRATION.—In
23 registering an emergency medical services agency
24 pursuant to paragraph (1), the Attorney General
25 shall allow such agency the option of a single reg-

1 istration in each State where the agency administers
2 controlled substances in lieu of requiring a separate
3 registration for each location of the emergency med-
4 ical services agency.

5 “(3) HOSPITAL-BASED AGENCY.—If a hospital-
6 based emergency medical services agency is reg-
7 istered under subsection (f), the agency may use the
8 registration of the hospital to administer controlled
9 substances in accordance with this subsection with-
10 out being registered under this subsection.

11 “(4) ADMINISTRATION OUTSIDE PHYSICAL
12 PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING
13 MEDICAL PROFESSIONAL.—Emergency medical serv-
14 ices professionals of a registered emergency medical
15 services agency may administer controlled sub-
16 stances in schedule II, III, IV, or V outside the
17 physical presence of a medical director or author-
18 izing medical professional in the course of providing
19 emergency medical services if the administration
20 is—

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

23 “(B) pursuant to—

24 “(i) a standing order that is issued
25 and adopted by one or more medical direc-

1 tors of the agency, including any such
2 order that may be developed by a specific
3 State authority; or

4 “(ii) a verbal order that is—

5 “(I) issued in accordance with a
6 policy of the agency; and

7 “(II) provided by a medical direc-
8 tor or authorizing medical professional
9 in response to a request by the emer-
10 gency medical services professional
11 with respect to a specific patient—

12 “(aa) in the case of a mass
13 casualty incident; or

14 “(bb) to ensure the proper
15 care and treatment of a specific
16 patient.

17 “(5) DELIVERY.—A registered emergency med-
18 ical services agency may deliver controlled sub-
19 stances from a registered location of the agency to
20 an unregistered location of the agency only if the
21 agency—

22 “(A) designates the unregistered location
23 for such delivery; and

1 “(B) notifies the Attorney General at least
2 30 days prior to first delivering controlled sub-
3 stances to the unregistered location.

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

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

8 “(B) at any designated location of the
9 agency or in an emergency services vehicle situ-
10 ated at a registered or designated location of
11 the agency; or

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

14 “(i) traveling from, or returning to, a
15 registered or designated location of the
16 agency in the course of responding to an
17 emergency; or

18 “(ii) otherwise actively in use by the
19 agency under circumstances that provide
20 for security of the controlled substances
21 consistent with the requirements estab-
22 lished by regulations of the Attorney Gen-
23 eral.

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 be
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 emergency medical services agencies, registered
6 locations, and designated locations to deliver
7 controlled substances to each other in the event
8 of—

9 “(i) shortages of such substances;

10 “(ii) a public health emergency; or

11 “(iii) a mass casualty event.

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

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

18 “(B) to override the authority of any State
19 to regulate the provision of emergency medical
20 services consistent with this subsection.

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

22 “(A) The term ‘authorizing medical profes-
23 sional’ means an emergency or other physician,
24 or another medical professional (including an

1 advanced practice registered nurse or physician
2 assistant)—

3 “(i) who is registered under this Act;

4 “(ii) who is acting within the scope of
5 the registration; and

6 “(iii) whose scope of practice under a
7 State license or certification includes the
8 ability to provide verbal orders.

9 “(B) The term ‘designated location’ means
10 a location designated by an emergency medical
11 services agency under paragraph (5).

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

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

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

24 “(ii) provides emergency medical serv-
25 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 “(E) 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 “(F) The term ‘emergency medical services
18 vehicle’ means an ambulance, fire apparatus,
19 supervisor truck, or other vehicle used by an
20 emergency medical services agency for the pur-
21 pose of providing or facilitating emergency med-
22 ical care and transport or transporting con-
23 trolled substances to and from the registered
24 and designated locations.

1 “(G) The term ‘hospital-based’ means,
2 with respect to an agency, owned or operated by
3 a hospital.

4 “(H) The term ‘medical director’ means a
5 physician who is registered under subsection (f)
6 and provides medical oversight for an emer-
7 gency medical services agency.

8 “(I) The term ‘medical oversight’ means
9 supervision of the provision of medical care by
10 an emergency medical services agency.

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

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

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

20 “(K) The term ‘registered location’ means
21 a location that appears on the certificate of reg-
22 istration issued to an emergency medical serv-
23 ices agency under this subsection or subsection
24 (f), which shall be where the agency receives
25 controlled substances from distributors.

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

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

16 “(N) The term ‘verbal order’ means an
17 oral directive that is given through any method
18 of communication including by radio or tele-
19 phone, directly to an emergency medical serv-
20 ices professional, to contemporaneously admin-
21 ister a controlled substance to individuals in
22 need of emergency medical services outside the
23 physical presence of the medical director or au-
24 thorizing medical professional.”.