

In the Senate of the United States,

October 24, 2017.

Resolved, That the bill from the House of Representatives (H.R. 304) entitled “An Act to amend the Controlled Substances Act with regard to the provision of emergency medical services.”, do pass with the following

AMENDMENT:

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 2017”.*

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

5 *Section 303 of the Controlled Substances Act (21*
6 *U.S.C. 823) is amended—*

7 *(1) by redesignating subsection (j) as subsection*
8 *(k); and*

9 *(2) by inserting after subsection (i) the following:*

1 “(j) *EMERGENCY MEDICAL SERVICES THAT ADMIN-*
2 *ISTER CONTROLLED SUBSTANCES.*—

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

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

14 “(B) *may deny an application for such reg-*
15 *istration if the Attorney General determines that*
16 *the issuance of such registration would be incon-*
17 *sistent with the requirements of this subsection*
18 *or the public interest based on the factors listed*
19 *in subsection (f).*

20 “(2) *OPTION FOR SINGLE REGISTRATION.*—*In*
21 *registering an emergency medical services agency pur-*
22 *suant to paragraph (1), the Attorney General shall*
23 *allow such agency the option of a single registration*
24 *in each State where the agency administers controlled*
25 *substances in lieu of requiring a separate registration*

1 *for each location of the emergency medical services*
2 *agency.*

3 “(3) *HOSPITAL-BASED AGENCY.—If a hospital-*
4 *based emergency medical services agency is registered*
5 *under subsection (f), the agency may use the registra-*
6 *tion of the hospital to administer controlled sub-*
7 *stances in accordance with this subsection without*
8 *being registered under this subsection.*

9 “(4) *ADMINISTRATION OUTSIDE PHYSICAL PRES-*
10 *ENCE OF MEDICAL DIRECTOR OR AUTHORIZING MED-*
11 *ICAL PROFESSIONAL.—Emergency medical services*
12 *professionals of a registered emergency medical serv-*
13 *ices agency may administer controlled substances in*
14 *schedule II, III, IV, or V outside the physical presence*
15 *of a medical director or authorizing medical profes-*
16 *sional in the course of providing emergency medical*
17 *services if the administration is—*

18 “(A) *authorized by the law of the State in*
19 *which it occurs; and*

20 “(B) *pursuant to—*

21 “(i) *a standing order that is issued*
22 *and adopted by one or more medical direc-*
23 *tors of the agency, including any such order*
24 *that may be developed by a specific State*
25 *authority; or*

1 “(ii) a verbal order that is—

2 “(I) issued in accordance with a
3 policy of the agency; and

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

9 “(aa) in the case of a mass
10 casualty incident; or

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

14 “(5) *DELIVERY.*—A registered emergency medical
15 services agency may deliver controlled substances from
16 a registered location of the agency to an unregistered
17 location of the agency only if the agency—

18 “(A) designates the unregistered location for
19 such delivery; and

20 “(B) notifies the Attorney General at least
21 30 days prior to first delivering controlled sub-
22 stances to the unregistered location.

23 “(6) *STORAGE.*—A registered emergency medical
24 services agency may store controlled substances—

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

1 “(B) at any designated location of the agen-
2 cy or in an emergency services vehicle situated at
3 a registered or designated location of the agency;
4 or

5 “(C) in an emergency medical services vehi-
6 cle used by the agency that is—

7 “(i) traveling from, or returning to, a
8 registered or designated location of the
9 agency in the course of responding to an
10 emergency; or

11 “(ii) otherwise actively in use by the
12 agency under circumstances that provide for
13 security of the controlled substances con-
14 sistent with the requirements established by
15 regulations of the Attorney General.

16 “(7) *NO TREATMENT AS DISTRIBUTION.*—The de-
17 livery of controlled substances by a registered emer-
18 gency medical services agency pursuant to this sub-
19 section shall not be treated as distribution for pur-
20 poses of section 308.

21 “(8) *RESTOCKING OF EMERGENCY MEDICAL*
22 *SERVICES VEHICLES AT A HOSPITAL.*—Notwith-
23 standing paragraph (13)(J), a registered emergency
24 medical services agency may receive controlled sub-
25 stances from a hospital for purposes of restocking an

1 *emergency medical services vehicle following an emer-*
2 *gency response, and without being subject to the re-*
3 *quirements of section 308, provided all of the fol-*
4 *lowing conditions are satisfied:*

5 *“(A) The registered or designated location of*
6 *the agency where the vehicle is primarily situ-*
7 *ated maintains a record of such receipt in ac-*
8 *cordance with paragraph (9).*

9 *“(B) The hospital maintains a record of*
10 *such delivery to the agency in accordance with*
11 *section 307.*

12 *“(C) If the vehicle is primarily situated at*
13 *a designated location, such location notifies the*
14 *registered location of the agency within 72 hours*
15 *of the vehicle receiving the controlled substances.*

16 *“(9) MAINTENANCE OF RECORDS.—*

17 *“(A) IN GENERAL.—A registered emergency*
18 *medical services agency shall maintain records*
19 *in accordance with subsections (a) and (b) of sec-*
20 *tion 307 of all controlled substances that are re-*
21 *ceived, administered, or otherwise disposed of*
22 *pursuant to the agency’s registration, without re-*
23 *gard to subsection 307(c)(1)(B).*

24 *“(B) REQUIREMENTS.—Such records—*

1 “(i) shall include records of deliveries
2 of controlled substances between all locations
3 of the agency; and

4 “(ii) shall be maintained, whether elec-
5 tronically or otherwise, at each registered
6 and designated location of the agency where
7 the controlled substances involved are re-
8 ceived, administered, or otherwise disposed
9 of.

10 “(10) *OTHER REQUIREMENTS.*—A registered
11 emergency medical services agency, under the super-
12 vision of a medical director, shall be responsible for
13 ensuring that—

14 “(A) all emergency medical services profes-
15 sionals who administer controlled substances
16 using the agency’s registration act in accordance
17 with the requirements of this subsection;

18 “(B) the recordkeeping requirements of
19 paragraph (9) are met with respect to a reg-
20 istered location and each designated location of
21 the agency;

22 “(C) the applicable physical security re-
23 quirements established by regulation of the Attor-
24 ney General are complied with wherever con-

1 *trolled substances are stored by the agency in ac-*
2 *cordance with paragraph (6); and*

3 *“(D) the agency maintains, at a registered*
4 *location of the agency, a record of the standing*
5 *orders issued or adopted in accordance with*
6 *paragraph (9).*

7 *“(11) REGULATIONS.—The Attorney General*
8 *may issue regulations—*

9 *“(A) specifying, with regard to delivery of*
10 *controlled substances under paragraph (5)—*

11 *“(i) the types of locations that may be*
12 *designated under such paragraph; and*

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

15 *“(B) specifying, with regard to the storage*
16 *of controlled substances under paragraph (6), the*
17 *manner in which such substances must be stored*
18 *at registered and designated locations, including*
19 *in emergency medical service vehicles; and*

20 *“(C) addressing the ability of hospitals,*
21 *emergency medical services agencies, registered*
22 *locations, and designated locations to deliver*
23 *controlled substances to each other in the event*
24 *of—*

25 *“(i) shortages of such substances;*

1 “(ii) a public health emergency; or

2 “(iii) a mass casualty event.

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

5 “(A) *to limit the authority vested in the At-*
6 *torney General by other provisions of this title to*
7 *take measures to prevent diversion of controlled*
8 *substances; or*

9 “(B) *to override the authority of any State*
10 *to regulate the provision of emergency medical*
11 *services consistent with this subsection.*

12 “(13) *DEFINITIONS.*—*In this section:*

13 “(A) *The term ‘authorizing medical profes-*
14 *sional’ means an emergency or other physician,*
15 *or another medical professional (including an*
16 *advanced practice registered nurse or physician*
17 *assistant)—*

18 “(i) *who is registered under this Act;*

19 “(ii) *who is acting within the scope of*
20 *the registration; and*

21 “(iii) *whose scope of practice under a*
22 *State license or certification includes the*
23 *ability to provide verbal orders.*

1 “(B) The term ‘designated location’ means a
2 location designated by an emergency medical
3 services agency under paragraph (5).

4 “(C) The term ‘emergency medical services’
5 means emergency medical response and emer-
6 gency mobile medical services provided outside of
7 a fixed medical facility.

8 “(D) The term ‘emergency medical services
9 agency’ means an organization providing emer-
10 gency medical services, including such an orga-
11 nization that—

12 “(i) is governmental (including fire-
13 based and hospital-based agencies), non-
14 governmental (including hospital-based
15 agencies), private, or volunteer-based;

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

18 “(iii) is authorized by the State in
19 which the organization is providing such
20 services to provide emergency medical care,
21 including the administering of controlled
22 substances, to members of the general public
23 on an emergency basis.

24 “(E) The term ‘emergency medical services
25 professional’ means a health care professional

1 *(including a nurse, paramedic, or emergency*
2 *medical technician) licensed or certified by the*
3 *State in which the professional practices and*
4 *credentialed by a medical director of the respec-*
5 *tive emergency medical services agency to pro-*
6 *vide emergency medical services within the scope*
7 *of the professional's State license or certification.*

8 “(F) *The term ‘emergency medical services*
9 *vehicle’ means an ambulance, fire apparatus, su-*
10 *pervisor truck, or other vehicle used by an emer-*
11 *gency medical services agency for the purpose of*
12 *providing or facilitating emergency medical care*
13 *and transport or transporting controlled sub-*
14 *stances to and from the registered and designated*
15 *locations.*

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

19 “(H) *The term ‘medical director’ means a*
20 *physician who is registered under subsection (f)*
21 *and provides medical oversight for an emergency*
22 *medical services agency.*

23 “(I) *The term ‘medical oversight’ means su-*
24 *pervision of the provision of medical care by an*
25 *emergency medical services agency.*

1 “(J) The term ‘registered emergency medical
2 services agency’ means—

3 “(i) an emergency medical services
4 agency that is registered pursuant to this
5 subsection; or

6 “(ii) a hospital-based emergency med-
7 ical services agency that is covered by the
8 registration of the hospital under subsection
9 (f).

10 “(K) The term ‘registered location’ means a
11 location that appears on the certificate of reg-
12 istration issued to an emergency medical services
13 agency under this subsection or subsection (f),
14 which shall be where the agency receives con-
15 trolled substances from distributors.

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

1 “(M) The term ‘standing order’ means a
2 written medical protocol in which a medical di-
3 rector determines in advance the medical criteria
4 that must be met before administering controlled
5 substances to individuals in need of emergency
6 medical services.

7 “(N) The term ‘verbal order’ means an oral
8 directive that is given through any method of
9 communication including by radio or telephone,
10 directly to an emergency medical services profes-
11 sional, to contemporaneously administer a con-
12 trolled substance to individuals in need of emer-
13 gency medical services outside the physical pres-
14 ence of the medical director or authorizing med-
15 ical professional.”.

Attest:

Secretary.

115TH CONGRESS
1ST SESSION

H.R. 304

AMENDMENT