115TH CONGRESS 1ST SESSION H.R.304

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 Ac3 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 sub-8 section (k); and

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

11 "(j) EMERGENCY MEDICAL SERVICES THAT ADMIN12 ISTER CONTROLLED SUBSTANCES.—

"(1) REGISTRATION.—For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III,
IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of
this subsection, the Attorney General—

"(A) shall register an emergency medical
services agency if the agency submits an application demonstrating it is authorized to conduct
such activity under the laws of each State in
which the agency practices; and

24 "(B) may deny an application for such reg25 istration if the Attorney General determines
26 that the issuance of such registration would be

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inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (f).

"(2) Option for single registration.—In 4 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

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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

emergency medical services agency pursuant to this
 subsection shall not be treated as distribution for
 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 sit15 uated maintains a record of such receipt in ac16 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	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-

vide emergency medical services within the scope of the professional's State license or certification.

"(E) The term 'emergency medical services 4 vehicle' means an ambulance, fire apparatus, 5 supervisor truck, or other vehicle used by an 6 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 emer18 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)

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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

authority within the State that may be adopted by medical directors.

3 "(M) The term 'standing order' means a
4 written medical protocol in which a medical di5 rector determines in advance the medical cri6 teria that must be met before administering
7 controlled substances to individuals in need of
8 emergency medical services.

"(N) The term 'verbal order' means an 9 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 January 9, 2017.

Attest:

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Clerk.

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