

115TH CONGRESS 1ST SESSION

H. R. 304

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

IN THE HOUSE OF REPRESENTATIVES

January 5, 2017

Mr. Hudson (for himself, Mr. Butterfield, Mrs. Wagner, Mr. Duncan of South Carolina, Mrs. Blackburn, Mr. Lipinski, Ms. Schakowsky, Ms. Beutler, Mr. Knight, Mr. Smith of Texas, Mr. Emmer, Mr. Billrakis, Mr. Abraham, Mr. Cummings, Mr. Cohen, Mr. Hastings, Mr. Ruiz, Ms. Kelly of Illinois, Mr. Roe of Tennessee, and Mr. Blumenauer) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Protecting Patient Ac-
- 5 cess to Emergency Medications Act of 2017".

1 SEC. 2. EMERGENCY MEDICAL SERVICES.

| 2 | Section 303 of the Controlled Substances Act (21 |
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| 3 | U.S.C. 823) is amended— |
| 4 | (1) by redesignating subsection (j) as sub- |
| 5 | section (k); and |
| 6 | (2) by inserting after subsection (i) the fol- |
| 7 | lowing: |
| 8 | "(j) Emergency Medical Services That Admin- |
| 9 | ISTER CONTROLLED SUBSTANCES.— |
| 10 | "(1) Registration.—For the purpose of ena- |
| 11 | bling emergency medical services professionals to ad- |
| 12 | minister controlled substances in schedule II, III, |
| 13 | IV, or V to ultimate users receiving emergency med- |
| 14 | ical services in accordance with the requirements of |
| 15 | this subsection, the Attorney General— |
| 16 | "(A) shall register an emergency medical |
| 17 | services agency if the agency submits an appli- |
| 18 | cation demonstrating it is authorized to conduct |
| 19 | such activity under the laws of each State in |
| 20 | which the agency practices; and |
| 21 | "(B) may deny an application for such reg- |
| 22 | istration if the Attorney General determines |
| 23 | that the issuance of such registration would be |
| 24 | inconsistent with the requirements of this sub- |
| 25 | section or the public interest based on the fac- |
| 26 | tors listed in subsection (f). |

- "(2) Option for single registration.—In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single reg-istration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency med-ical services agency.
 - "(3) Hospital-Based agency.—If a hospital-based emergency medical services agency is registered under subsection (f), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.
 - "(4) Administration outside physical presence of medical director or authorizing medical professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

| 1 | "(A) authorized by the law of the State in |
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| 2 | which it occurs; and |
| 3 | "(B) pursuant to— |
| 4 | "(i) a standing order that is issued |
| 5 | and adopted by one or more medical direc- |
| 6 | tors of the agency, including any such |
| 7 | order that may be developed by a specific |
| 8 | State authority; or |
| 9 | "(ii) a verbal order that is— |
| 10 | "(I) issued in accordance with a |
| 11 | policy of the agency; |
| 12 | "(II) provided by an authorizing |
| 13 | medical professional in response to a |
| 14 | request by the emergency medical |
| 15 | services professional with respect to a |
| 16 | specific patient; |
| 17 | "(III) in the case of a mass cas- |
| 18 | ualty incident; or |
| 19 | "(IV) to ensure the proper care |
| 20 | and treatment of a specific patient. |
| 21 | "(5) Delivery.—A registered emergency med- |
| 22 | ical services agency may deliver controlled sub- |
| 23 | stances from a registered location of the agency to |
| 24 | an unregistered location of the agency only if— |

| 1 | "(A) the agency designates the unregis- |
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| 2 | tered location for such delivery; and |
| 3 | "(B) notifies the Attorney General at least |
| 4 | 30 days prior to first delivering controlled sub- |
| 5 | stances to the unregistered location. |
| 6 | "(6) Storage.—A registered emergency med- |
| 7 | ical services agency may store controlled sub- |
| 8 | stances— |
| 9 | "(A) at a registered location of the agency; |
| 10 | "(B) at any designated location of the |
| 11 | agency or in an emergency services vehicle situ- |
| 12 | ated at a registered or designated location of |
| 13 | the agency; or |
| 14 | "(C) in an emergency medical services ve- |
| 15 | hicle used by the agency that is— |
| 16 | "(i) traveling from, or returning to, a |
| 17 | registered or designated location of the |
| 18 | agency in the course of responding to an |
| 19 | emergency; or |
| 20 | "(ii) otherwise actively in use by the |
| 21 | agency. |
| 22 | "(7) NO TREATMENT AS DISTRIBUTION.—The |
| 23 | delivery of controlled substances by a registered |
| 24 | emergency medical services agency pursuant to this |

subsection shall not be treated as distribution for purposes of section 308.

- "(8) Restocking of Emergency Medical Services vehicles at a Hospital.—Notwith-standing paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 308, provided all of the following conditions are satisfied:
 - "(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).
 - "(B) The hospital maintains a record of such delivery to the agency in accordance with section 307.
 - "(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.
- 24 "(9) Maintenance of Records.—

| 1 | "(A) IN GENERAL.—A registered emer- |
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| 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 |
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| 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, |
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| 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- |
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| 2 side of a fix | xed medical facility. |
| 3 "(C) T | The term 'emergency medical services |
| 4 agency' me | ans an organization providing emer- |
| 5 gency medi | cal services, including such an orga- |
| 6 nization tha | at— |
| 7 " | (i) is governmental (including fire- |
| 8 based | and hospital-based agencies), non- |
| 9 govern | mental (including hospital-based |
| 10 agenci | es), private, or volunteer-based; |
| 11 " | (ii) provides emergency medical serv- |
| ices by | ground, air, or otherwise; and |
| 13 " | (iii) is authorized by the State in |
| 14 which | the organization is providing such |
| 15 service | es to provide emergency medical care, |
| 16 includi | ing the administering of controlled |
| 17 substa | nces, to members of the general pub- |
| lic on | an emergency basis. |
| 19 "(D) <i>T</i> | The term 'emergency medical services |
| 20 professiona | l' means a health care professional |
| 21 (including | a nurse, paramedic, or emergency |
| 22 medical tec | chnician) licensed or certified by the |
| State in w | which the professional practices and |
| 24 credentialed | d by a medical director of the respec- |
| 25 tive emerge | ency medical services agency to pro- |

| 1 | vide emergency medical services within the |
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| 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 |

practice registered nurse or physician assistant)

| 1 | whose scope of practice under a State license or |
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| 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 |

the geographic jurisdiction of such agency or

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

"(M) The term 'standing order' means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

"(N) The term 'verbal order' means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the authorizing medical director.".

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