

Public Law 115–83
115th Congress

An Act

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

Nov. 17, 2017
[H.R. 304]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Protecting Patient Access to Emergency Medications Act of 2017”.

Protecting
Patient Access to
Emergency
Medications Act
of 2017.
21 USC 801 note.

SEC. 2. EMERGENCY MEDICAL SERVICES.

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

- (1) by redesignating subsection (j) as subsection (k); and
- (2) by inserting after subsection (i) the following:

“(j) **EMERGENCY MEDICAL SERVICES THAT ADMINISTER 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

“(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be 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 registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical 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 PROFESSIONAL.**—Emergency medical services 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—

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

“(B) pursuant to—

“(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

“(ii) a verbal order that is—

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

“(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

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

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

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

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

“(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

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

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

“(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

“(C) in an emergency medical services vehicle used by the agency that is—

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

“(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

“(7) NO TREATMENT AS DISTRIBUTION.—The 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.

“(8) RESTOCKING OF EMERGENCY MEDICAL SERVICES VEHICLES AT A HOSPITAL.—Notwithstanding 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

Notification.
Time period.

Records.

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.

Notification.
Deadline.

“(9) MAINTENANCE OF RECORDS.—

“(A) IN GENERAL.—A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 307 of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency’s registration, without regard to subsection 307(c)(1)(B).

“(B) REQUIREMENTS.—Such records—

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

“(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

“(10) OTHER REQUIREMENTS.—A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

“(A) all emergency medical services professionals who administer controlled substances using the agency’s registration act in accordance with the requirements of this subsection;

“(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

“(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

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

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

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

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

“(ii) the manner in which a notification under paragraph (5)(B) must be made;

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

“(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated

locations to deliver controlled substances to each other in the event of—

- “(i) shortages of such substances;
- “(ii) a public health emergency; or
- “(iii) a mass casualty event.

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

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

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

“(13) DEFINITIONS.—In this section:

“(A) The term ‘authorizing medical professional’ means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

- “(i) who is registered under this Act;
- “(ii) who is acting within the scope of the registration; and
- “(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

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

“(C) The term ‘emergency medical services’ means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

“(D) The term ‘emergency medical services agency’ means an organization providing emergency medical services, including such an organization that—

- “(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;
- “(ii) provides emergency medical services by ground, air, or otherwise; and
- “(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

“(E) The term ‘emergency medical services professional’ means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional’s State license or certification.

“(F) The term ‘emergency medical services vehicle’ means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

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

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

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

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

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

“(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (f).

“(K) The term ‘registered location’ means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (f), which shall be where the agency receives controlled substances from distributors.

“(L) The term ‘specific State authority’ means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding 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 medical director or authorizing medical professional.”.

Approved November 17, 2017.

LEGISLATIVE HISTORY—H.R. 304:

CONGRESSIONAL RECORD, Vol. 163 (2017):

Jan. 9, considered and passed House.

Oct. 24, considered and passed Senate, amended.

Nov. 2, House concurred in Senate amendment.