

114TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. CASSIDY introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Controlled Substances Act with respect 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 2016”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds that—

8 (1) the use of controlled substances by emer-
9 gency medical services agencies to administer med-
10 ical care and medicines to individuals in the field is

1 essential to save lives, manage pain, and improve
2 health outcomes;

3 (2) the unique nature of mobile emergency
4 medical services is unlike other healthcare services
5 governed by the Controlled Substances Act (21
6 U.S.C. 801 et seq.) in that it requires the provision
7 of time-sensitive and mobile medical care to individ-
8 uals with critical injuries and illnesses in the field
9 and movement of such individuals to definitive care;

10 (3) there have been few investigations by the
11 Drug Enforcement Administration related to diver-
12 sion in emergency medical services;

13 (4) 1 recent survey of large emergency medical
14 services agencies in the United States showed less
15 than 20 diversions or investigations for nearly
16 70,000 doses of controlled substances administered;

17 (5) regulatory oversight to prevent diversion is
18 essential in all health care settings, including emer-
19 gency medical services;

20 (6) such oversight shall be carefully tailored to
21 recognize unique care delivery models, including the
22 provision of medical care to individuals by emer-
23 gency medical services practitioners under the super-
24 vision of a physician medical director; and

1 (7) such oversight should further promote uni-
2 formity of rules, application and enforcement to pre-
3 vent diversion and establish clear guidelines within
4 emergency medical services while also recognizing
5 the variety of emergency medical services agencies
6 including governmental, nongovernmental, private,
7 and volunteer emergency medical services agencies.

8 **SEC. 3. EMERGENCY MEDICAL SERVICES.**

9 Part C of the Controlled Substances Act (21 U.S.C.
10 821 et seq.) is amended by adding at the end the fol-
11 lowing:

12 **“SEC. 312. EMERGENCY MEDICAL SERVICES.**

13 “(a) DEFINITIONS.—In this section—

14 “(1) the term ‘emergency medical services’
15 means emergency medical response, and emergency
16 mobile medical services, provided outside of a med-
17 ical facility.

18 “(2) the term ‘emergency medical services agen-
19 cy’ means an organization providing emergency med-
20 ical services, including an organization that—

21 “(A) is governmental (including a fire-
22 based agency), nongovernmental (including a
23 hospital-based agency), private, or volunteer-
24 based; and

1 “(B) provides emergency medical services
2 by ground, air, or otherwise;

3 “(3) the term ‘emergency medical services prac-
4 titioner’ means a health care practitioner (including
5 a nurse, a paramedic, or an emergency medical tech-
6 nician) licensed or certified by a State and
7 credentialed by a medical director of the respective
8 emergency medical services agency to provide emer-
9 gency medical services to individuals within the
10 scope of the State license or certification of the prac-
11 titioner;

12 “(4) the term ‘medical director’ means a physi-
13 cian providing medical oversight for an emergency
14 medical services agency;

15 “(5) the term ‘medical oversight’ means super-
16 vision of medical operations of an emergency medical
17 services agency;

18 “(6) the term ‘standing order’ means a written
19 medical protocol in which a medical director pre-
20 scribes in advance the medical criteria to be followed
21 by emergency medical services practitioners in ad-
22 ministering a controlled substance to an individual
23 in need of emergency medical services;

24 “(7) the term ‘verbal order’ means a verbal pre-
25 scription to be followed by an emergency medical

1 services practitioner in administering a controlled
2 substance to an individual in need of emergency
3 medical services;

4 “(8) the term ‘online medical direction’ means
5 verbal instructions provided by a physician to an
6 emergency medical services practitioner with regard
7 to patient care and treatment, including by radio or
8 telephone; and

9 “(9) the term ‘registrant emergency medical
10 services agency’ means an emergency medical serv-
11 ices agency that registers under subsection (b) or a
12 hospital that—

13 “(A) owns and operates an emergency
14 medical services agency; and

15 “(B) is registered under its own hospital li-
16 cense.

17 “(b) REGISTRATION.—

18 “(1) IN GENERAL.—For the purpose of ena-
19 bling emergency medical services practitioners to
20 dispense controlled substances in schedule II, III,
21 IV, or V to ultimate users receiving emergency med-
22 ical services, the Attorney General shall, at the re-
23 quest of the emergency medical services agency em-
24 ploying such practitioners, register such emergency
25 medical services agency under section 303(f) in lieu

1 of registering the individual practitioners or 1 or
2 more medical directors of such agency.

3 “(2) SINGLE REGISTRATION.—In registering an
4 emergency medical services agency pursuant to para-
5 graph (1), the Attorney General shall require a sin-
6 gle registration per State, not a separate registration
7 for each location of the emergency medical services
8 agency.

9 “(3) GUIDANCE TO REGISTRANTS.—For pur-
10 poses of providing guidance to registrant emergency
11 medical services agencies, the Attorney General shall
12 tailor such guidance to recognize—

13 “(A) the existing delivery of medical care
14 and medical oversight to patients with emer-
15 gency medical conditions; and

16 “(B) the variety of emergency medical
17 service care delivery models provided by emer-
18 gency medical services agencies.

19 “(c) MEDICAL OVERSIGHT.—

20 “(1) IN GENERAL.—Notwithstanding section
21 309—

22 “(A) a registrant emergency medical serv-
23 ices agency shall have 1 or more medical direc-
24 tors responsible for medical oversight of the

1 provision of emergency medical services by the
2 agency;

3 “(B) the medical director shall be a physi-
4 cian licensed by the state in which the physician
5 practices medicine and in which the emergency
6 medical services agency is located;

7 “(C) subject to the authority provided by
8 the State or a political subdivision or other del-
9 egated authority of such State, the responsibil-
10 ities of the medical director may include—

11 “(i) decisions with regard to transpor-
12 tation destination of patients;

13 “(ii) approving all medical protocols,
14 including standing orders;

15 “(iii) overseeing patient care delivered
16 by emergency medical services practitioners
17 of the emergency medical services agency,
18 including—

19 “(I) the evaluation, treatment,
20 and interventions of patients,

21 “(II) online medical direction;
22 and

23 “(III) establishing drug
24 formularies and the dispensing and

1 administering of all medications and
2 controlled substances to patients;

3 “(iv) overseeing medical education
4 and training programs for emergency med-
5 ical services practitioners; and

6 “(v) overseeing quality improvement
7 for the emergency medical services agency;
8 and

9 “(D) subject to the authority provided by
10 the State or a political subdivision or other del-
11 egated authority of such State, controlled sub-
12 stances in schedule II, III, IV or V may be ad-
13 ministered by the emergency medical services
14 practitioners of a registrant emergency medical
15 services agency in the course of providing emer-
16 gency medical services pursuant to—

17 “(i) a standing order issued by 1 or
18 more medical directors of such agency; or

19 “(ii) an online medical direction that
20 includes a verbal order issued by 1 or more
21 medical directors, or other licensed physi-
22 cian, in accordance with a policy of such
23 agency under the following cir-
24 cumstances—

1 “(I) the emergency medical serv-
2 ices practitioners request such an
3 order with regard to a specific patient
4 and the medical director verbally pro-
5 vides such an order;

6 “(II) the medical director pro-
7 vides verbal orders upon dispatching
8 emergency medical services practi-
9 tioners responding to an unanticipated
10 mass casualty incident; or

11 “(III) other specific patient situ-
12 ations in which the medical director
13 identifies a need to provide such an
14 order to ensure proper care and treat-
15 ment to patients.

16 “(2) IMPERMISSIBLE LIMITATIONS ON ALLOW-
17 ABLE PRESCRIPTIONS.—In the case of administering
18 a controlled substance under paragraph (1), the
19 medical directors of the registrant emergency med-
20 ical services agency shall not be required—

21 “(A) to be present; or

22 “(B) to provide a written or oral prescrip-
23 tion with regard to a known individual before or
24 at the time of such administering.

25 “(3) DOCUMENTATION.—

1 “(2) MOVEMENT AND DELIVERY.—The reg-
2 istrant emergency medical services agency may move
3 or deliver controlled substances within the possession
4 of such agency between any locations of such agen-
5 cy. A registrant emergency medical services agency
6 shall not be treated as a distributor of controlled
7 substances under this Act by reason of such move-
8 ment or distribution.

9 “(3) STORAGE.—Such agency—

10 “(A) may store controlled substances at
11 any location of the agency designated by the
12 agency for such storage; and

13 “(B) may not store controlled substances
14 at any location not so designated.

15 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
16 tion shall be construed to—

17 “(1) alter any requirements under titles XVIII
18 or XIX of the Social Security Act; or

19 “(2) limit the authority vested in the Attorney
20 General to enforce diversion of controlled substances
21 otherwise provided in this Act.”.