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.

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 2016”.

SEC. 2. FINDINGS.

The Congress finds that—

(1) the use of controlled substances by emergency medical services agencies to administer medical care and medicines to individuals in the field is
essential to save lives, manage pain, and improve health outcomes;

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

(3) there have been few investigations by the Drug Enforcement Administration related to diversion in emergency medical services;

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

(5) regulatory oversight to prevent diversion is essential in all health care settings, including emergency medical services;

(6) such oversight shall be carefully tailored to recognize unique care delivery models, including the provision of medical care to individuals by emergency medical services practitioners under the supervision of a physician medical director; and
(7) such oversight should further promote uniformity of rules, application and enforcement to prevent diversion and establish clear guidelines within emergency medical services while also recognizing the variety of emergency medical services agencies including governmental, nongovernmental, private, and volunteer emergency medical services agencies.

SEC. 3. EMERGENCY MEDICAL SERVICES.

Part C of the Controlled Substances Act (21 U.S.C. 821 et seq.) is amended by adding at the end the following:

“SEC. 312. EMERGENCY MEDICAL SERVICES.

“(a) DEFINITIONS.—In this section—

“(1) the term ‘emergency medical services’ means emergency medical response, and emergency mobile medical services, provided outside of a medical facility.

“(2) the term ‘emergency medical services agency’ means an organization providing emergency medical services, including an organization that—

“(A) is governmental (including a fire-based agency), nongovernmental (including a hospital-based agency), private, or volunteer-based; and
“(B) provides emergency medical services by ground, air, or otherwise;

“(3) the term ‘emergency medical services practitioner’ means a health care practitioner (including a nurse, a paramedic, or an emergency medical technician) licensed or certified by a State and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services to individuals within the scope of the State license or certification of the practitioner;

“(4) the term ‘medical director’ means a physician providing medical oversight for an emergency medical services agency;

“(5) the term ‘medical oversight’ means supervision of medical operations of an emergency medical services agency;

“(6) the term ‘standing order’ means a written medical protocol in which a medical director prescribes in advance the medical criteria to be followed by emergency medical services practitioners in administering a controlled substance to an individual in need of emergency medical services;

“(7) the term ‘verbal order’ means a verbal prescription to be followed by an emergency medical
services practitioner in administering a controlled
substance to an individual in need of emergency
medical services;

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

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

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

“(B) is registered under its own hospital li-

cense.

“(b) REGISTRATION.—

“(1) IN GENERAL.—For the purpose of ena-
bring emergency medical services practitioners to
dispense controlled substances in schedule II, III,
IV, or V to ultimate users receiving emergency med-
ical services, the Attorney General shall, at the re-
quiest of the emergency medical services agency em-
ploying such practitioners, register such emergency
medical services agency under section 303(f) in lieu
of registering the individual practitioners or 1 or
more medical directors of such agency.

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

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

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

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

“(c) MEDICAL OVERSIGHT.—

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

“(A) a registrant emergency medical serv-
ices agency shall have 1 or more medical direc-
tors responsible for medical oversight of the
provision of emergency medical services by the agency;

“(B) the medical director shall be a physician licensed by the state in which the physician practices medicine and in which the emergency medical services agency is located;

“(C) subject to the authority provided by the State or a political subdivision or other delegated authority of such State, the responsibilities of the medical director may include—

“(i) decisions with regard to transportation destination of patients;

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

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

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

“(II) online medical direction;

and

“(III) establishing drug formularies and the dispensing and
administering of all medications and
calculated substances to patients;
“(iv) overseeing medical education
and training programs for emergency med-
cial services practitioners; and
“(v) overseeing quality improvement
for the emergency medical services agency;
and
“(D) subject to the authority provided by
the State or a political subdivision or other del-
egated authority of such State, controlled sub-
stances in schedule II, III, IV or V may be ad-
ministered by the emergency medical services
practitioners of a registrant emergency medical
services agency in the course of providing emer-
gency medical services pursuant to—
“(i) a standing order issued by 1 or
more medical directors of such agency; or
“(ii) an online medical direction that
includes a verbal order issued by 1 or more
medical directors, or other licensed physi-
cian, in accordance with a policy of such
agency under the following cir-
cumstances—
“(I) the emergency medical services practitioners request such an order with regard to a specific patient and the medical director verbally provides such an order;

“(II) the medical director provides verbal orders upon dispatching emergency medical services practitioners responding to an unanticipated mass casualty incident; or

“(III) other specific patient situations in which the medical director identifies a need to provide such an order to ensure proper care and treatment to patients.

“(2) Imperm issible Limitations On allowable Prescriptions.—In the case of administering a controlled substance under paragraph (1), the medical directors of the registrant emergency medical services agency shall not be required—

“(A) to be present; or

“(B) to provide a written or oral prescription with regard to a known individual before or at the time of such administering.

“(3) Documentation.—
“(A) IN GENERAL.—A registrant emergency medical services agency shall keep any such standing order on file and make such standing order available to the Attorney General upon the request of the Attorney General.

“(B) POLICY.—A registrant emergency medical services agency shall have a policy requiring practitioners to document in the patient care chart a verbal order was received from online medical direction and a controlled substance was administered. Any such administration of a controlled substance shall be documented in the patient care chart as soon as practicable and available to the Attorney General upon the request of the Attorney General.

“(d) RECEIPT, MOVEMENT, AND STORAGE OF CONTROLLED SUBSTANCES.—

“(1) RECEIPT.—The registrant emergency medical services agency—

“(A) may receive controlled substances at any location of the agency designated by the agency for such receipt; and

“(B) may not receive controlled substances at any location not so designated.
“(2) MOVEMENT AND DELIVERY.—The registrant emergency medical services agency may move or deliver controlled substances within the possession of such agency between any locations of such agency. A registrant emergency medical services agency shall not be treated as a distributor of controlled substances under this Act by reason of such movement or distribution.

“(3) STORAGE.—Such agency—

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

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

“(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

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

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