



Public Health Law

Center for State, Tribal, Local, and Territorial Support (*proposed*)
Centers for Disease Control and Prevention

The Protecting Patient Access to Emergency Medications Act of 2017

In 1970, the federal Controlled Substances Act¹ (CSA) was created to regulate substances that have the potential to be abused. At the time, the CSA lacked instructions for the maintenance and use of these substances by emergency medical services (EMS). States, therefore, created their own EMS-related controlled substances requirements. In 2017, the Protecting Patient Access to Emergency Medications Act (PPAEMA) was introduced in the United States Congress to amend the CSA to include EMS requirements and end confusion among states and EMS agencies. The PPAEMA was signed into law on November 17, 2017.²

EMS Overlooked by Controlled Substances Act of 1970

EMS agencies primarily use controlled substances such as opioids and benzodiazepines for advanced life support patient care.³ However, until 2017, the CSA lacked guidance regarding administration of controlled substances by EMS agencies and EMS personnel.⁴ The lack of direction led to confusion in the EMS field and caused several states to create their own EMS-related regulations.⁵ Prior to 2017, the CSA required physicians, pharmacists, manufacturers, and researchers to register with the United States Drug Enforcement Administration (DEA) before making, distributing, administering, or studying substances on the national list of controlled substances.⁶ As the CSA did not specifically mention EMS, state governments and EMS agencies interpreted the CSA to allow an EMS agency to administer controlled substances under the DEA registration of the medical director or hospital overseeing the agency's patient care.⁷

DEA Rejection of Standing Orders

When creating EMS-related controlled substances laws, some states allowed for the use of standing orders.⁸ Standing orders are written protocols, pre-approved by a medical director, which allow EMS professionals to use certain medical procedures for patients exhibiting particular medical conditions. Standing orders are commonly used in the practice of prehospital emergency medicine and allow EMS personnel to provide emergency care—without needing to call a doctor for treatment instructions—for each patient they encounter.⁹

In a 2011 letter to a Kentucky paramedic, the DEA asserted that the CSA did not allow for dispensing of controlled substances under a standing order. The DEA justified its statement by noting that administration of controlled substances must be “patient and issue specific” and “for a legitimate medical purpose by an individual practitioner in the usual course of his or her professional practice.”¹⁰ However, the DEA did not enforce that position for several years. In 2014, DEA representatives at the annual meetings of the American College of Emergency Physicians and the National Association of EMS Physicians announced the DEA's intention to promulgate rules regarding the use of controlled substances by EMS. These proposed regulations would have banned the use of standing orders.¹¹



The proposed DEA regulation prompted the introduction of the PPAEMA.¹²

New Controlled Substances Requirements for EMS under PPAEMA

The PPAEMA amended Section 33 of the CSA to include DEA registration for EMS agencies, approved uses of standing orders, and requirements for the maintenance and administration of controlled substances used by EMS agencies.

DEA Registration for EMS Agencies. Language added by PPAEMA now allows EMS agencies to receive their own DEA registration to administer controlled substances. Key factors of this new registration include the following:

- EMS agencies that service multiple states will need DEA registrations for each of those states
- Hospital-based EMS agencies may use the hospital's DEA registration and will not need to register with the DEA separately¹³

Use of Standing Orders. The PPAEMA allows EMS agencies to “administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional.”¹⁴ To do so, the EMS agency must 1) be authorized to do so by state law and 2) have a standing order¹⁵ or verbal order¹⁶ from a medical director or an authorizing medical professional.¹⁷

Storage of Controlled Substances. EMS agencies may store controlled substances in the agency location registered with the DEA, unregistered locations, and in EMS vehicles used by the agency. The United States Attorney General must be notified of all unregistered locations at least 30 days before the controlled substances are initially delivered to those locations.¹⁸

Restocking EMS Vehicles at Hospitals. Following an emergency response, EMS agencies may restock their EMS vehicles with controlled substances from a hospital without completing CSA order forms.¹⁹

Maintenance of Controlled Substance Records. EMS agencies must follow record requirements stated in the CSA.²⁰ These requirements include recording all deliveries of controlled substances and storing records in the locations where controlled substances are received, administered, and discarded.²¹

EMS Agency Liability. EMS agencies, under their medical director's supervision, are now liable for ensuring the proper use, maintenance, reporting, and security of controlled substances used by the agency.²² Before the PPAEMA, liability regarding use of controlled substances by an EMS agency was placed on the DEA-registered medical director or the hospital overseeing the agency.

Conclusion

After years of confusion, PPAEMA amended the CSA to include rules for use of controlled substances by EMS agencies. Along with providing instruction on the maintenance of controlled substances, federal law now allows EMS agencies to apply for their own DEA registration and administer controlled substances under standing orders.

Acknowledgments and Disclaimers

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Published May 30, 2018.

¹ Controlled Substances Act of 1970, Pub.L. 91–513, Title II, 84 Stat. 1242.

² Protecting Patient Access to Emergency Medications Act of 2017, Pub.L. 115-83, 131 Stat. 1267 (amending 21 U.S.C. § 823 (2017)).

³ Opioids are used to manage pain in patients suffering from fractures, trauma, and other painful medical conditions. Benzodiazepines are used to stop potentially life-threatening seizures. See Patient Care, QI and General Safety Comm., National Emergency Medical Services Advisory Council, EMS Utilization of Controlled Substances (2017).

⁴ 21 U.S.C. § 823 (2016).

⁵ See e.g. D.C. Code § 48-931.02 (2017), S.C. Code Ann. § 44-61-130 (2017), and N.H. Rev. Stat. Ann. § 318-B:10 (2017).

⁶ 21 U.S.C § 823 (2016). The current list of controlled substances can be found on the DEA website or in 21 C.F.R. §1308.

⁷ See e.g. Or. Admin. R. 333-250-0300 (2017), Fla. Admin. Code r. 64J-1.004 (2017), and N.D. Admin. Code 61-09-01-01 (2017).

⁸ See e.g. N.D. Admin. Code 61-09-01-01 (2017), N.Y Comp. Codes R. & Regs. 10, §80.136 (2017), and 172 Neb. Admin. Code Ch. 12 §004.

⁹ Strengthening our National Trauma System: Hearing on H.R. 4365 Before the Subcomm. On Health of the H. Comm. on Energy and Commerce, 114th Cong. 1-3 (2016) (Statement of Craig Manifold, D.O., F.A.C.E.P., Chairman, American College of Emergency Physicians).

¹⁰ Letter from John W. Partridge, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Admin., U.S. Dep't of Justice, to Jeremy R. Urekew, Paramedic, Anchorage Fire & Ambulance Dist. (Dec. 19, 2011) (on file with the Nat'l Ass'n of State EMS Officials).

¹¹ Strengthening our National Trauma System: Hearing on H.R. 4365 Before the Subcomm. On Health of the H. Comm. on Energy and Commerce, 114th Cong. 4 (2016) (Statement of Craig Manifold, D.O., F.A.C.E.P., Chairman, American College of Emergency Physicians).

¹² Protecting Patient Access to Emergency Medications Act, H.R. 304, 115th Cong. (2017).

¹³ 21 U.S.C. §§ 823(j)(1)-(3) (2017).

¹⁴ *Id.* § 823(j)(4); "Medical director" is defined as a physician registered with the DEA to administer controlled substances and who provides medical oversight to an EMS agency. See 21 U.S.C § 823(j)(13)(H) (2017).

¹⁵ “Standing order” is defined as “a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances” to EMS patients. See 21 U.S.C § 823(j)(13)(M) (2017).

¹⁶ “Verbal order” is defined as “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.” See 21 U.S.C § 823(j)(13)(N) (2017).

¹⁷ 21 U.S.C. § 823(j)(4).

¹⁸ *Id.* § 823(j)(6).

¹⁹ *Id.* § 823(j)(8).

²⁰ Record requirements can be found in the Controlled Substances Act of 1970 at 21 U.S.C. §§827(a)-(b).

²¹ 21 U.S.C. § 823(j)(9) (2017).

²² *Id.* § 823(j)(10).