



Protecting Patient Access to Emergency Medications Act of 2017

A practical Implementation Guide for Indiana EMS Provider
Agencies

8/24/2021

EMS and Controlled Substances



- Every day across the State of Indiana, EMS is utilizing controlled substances to provide emergency care to patients.
- Controlled substances are medications such as fentanyl, morphine, ativan, valium, or ketamine, just to name a few.
- Historically, these medications have been provided to EMS by hospitals under written affiliation agreements or by the agencies EMS Medical Director using a practitioner federal Drug Enforcement Agency (DEA) registration.
- While these practices were allowed by the federal Drug Enforcement Agency, the process was ambiguous and not well established in written statute.

HR304 – Now Public Law No: 115-83



- In 2017, the 115th US Congress passed HR304
- The Protecting Patient Access to Emergency Medications Act of 2017.
 - This law amends the Controlled Substances Act of 1971.
 - Specifies that EMS agencies are permitted to have one DEA registration, rather than having separate registrations for each EMS location (ambulance).



The Protecting Patient Access to Emergency Medications Act of 2017



- Authorizes EMS professionals to administer controlled substances outside the physical presence of a medical director or authorizing medical professional through standing or verbal orders (aka Guidelines or Protocols.)
- Allows EMS agencies to register with the state to be able to administer controlled substances. An EMS agency only needs to obtain one registration per state regardless of how many locations they operate in within that state.
- Includes a variety of other requirements for how registered EMS agencies must deliver controlled substances, store controlled substances, restock EMS vehicles, maintain records, and otherwise conduct their operations

The Protecting Patient Access to Emergency Medications Act of 2017



- For more information on the Protecting Patient Access to Emergency Medication Act of 2017, including the proposed rules for implementation, please visit the federal registrar at
- <https://www.federalregister.gov/documents/2020/10/05/2020-21675/registering-emergency-medical-services-agencies-under-the-protecting-patient-access-to-emergency>

Planning for DEA/CSR for EMS Providers



- In order for Indiana to become compliant with Public Law No: 115-83 several things needed to happen.
 - The Indiana Board of Pharmacy needed to change their rules that in the past waived EMS provider agencies from obtaining a state Controlled Substance Registration (CSR).
 - A State CSR is required prior to applying for and receiving a federal DEA registration.
 - Once a CSR has been granted, an application can then be filed with the DEA for an EMS provider agency DEA Registration.



CSR Rule Change



- On July 30th, 2021, The Indiana Board of Pharmacy rule pertaining to EMS provider agencies utilization of a State of Indiana CSR was signed into law.
- This allows EMS provider agencies needing to carry and administer controlled substances to obtain a State CSR.
- Under the new rule changes, only EMS provider organizations that are **owned and operated** by a hospital are permitted to operate under the hospital's existing CSR and DEA licenses.
- The rule references: “A separate registration is required for each principal place of business where controlled substances are stored.” A DEA license (and hence a CSR) is required for any location where drugs are ordered, stocked or stored. While the DEA and new CSR rules allow for EMS to have a single central stock, they can keep controlled substances on each of their ambulances for patient use without triggering the need for additional registrations. However, they would be required to have a separate CSR and DEA license if they stock an additional cache of drugs outside the ambulance at a base or building.
- This will require all other EMS provider organizations to obtain a State CSR moving forward.
- This rule will go into effect on 8/25/2021.

Overview of New Requirements for EMS Controlled Substance Administration



EMS Organization not owned or operated by a hospital

Obtain Indiana Controlled Substance Registration (CSR)

Obtain Federal DEA Registration

Step 1



- Start a discussion with your current DEA Registrant about your process moving forward. In most instances, this will be
 - Your supervising hospital, or
 - Your EMS Medical Director
- Applying for and obtaining an EMS provider agency State CSR and Federal DEA license will likely provide you with greater feasibility, flexibility, and accountability for controlled substances.
- Your EMS Medical Director will still be integral to the protocols and guidelines for the use/administration of these substances.
- Discuss the new process with all key stakeholders before proceeding.
- Even pharmacies and medical suppliers are also impacted by the PL No. 115-83 and some have begun scrutinizing EMS eligibility for drug orders in some places.

Step 2



- Review your own policies and procedures for how your EMS provider agency handles and administers controlled substances. This includes, but is not limited to the following:
 - Your process for ordering controlled substances
 - Your process for receiving and handling controlled substances
 - Your safeguards for storage and distribution of controlled substances
 - Your guidelines and protocols for the administration of controlled substances
 - How you track and review your use of controlled substances
 - Your process for loss, theft, diversion, and expiration of controlled substances
 - For more information, please review all applicable state and federal policies on controlled substances.

Step 3



- In order to obtain a federal DEA registration, you must first obtain a State Controlled Substance Registration (CSR.)
- To do this, navigate to the Indiana Board of Pharmacy Website.
- <https://www.in.gov/pla/professions/indiana-controlled-substances-advisory-committee/application-and-information/non-practitioner-controlled-substances-registration/>
- You must obtain your official CSR from Indiana before you can register with the DEA.

Step 4



- Once you have obtained your CSR from the State of Indiana, you can then apply for your federal DEA registration.
- <https://apps.dea.diversion.usdoj.gov/webforms2/spring/main?execution=e1s1>
- Chose the Mid Level Practitioner option and follow the instructions.

Select Your Business Category

Form 224

[Practitioner \(MD, DO, DDS, DMD, DVM, DPM\)](#)
[Mid Level Practitioner \(NP, PA, OD, etc.\)](#)
[Pharmacy](#)
[Hospital/Clinic](#)
[Teaching Institution](#)

Form 225

[Manufacturer](#)
[Importer](#)
[Exporter](#)
[Distributor](#)
[Reverse Distributor](#)
[Researcher](#)
[Canine Handler](#)
[Analytical Lab](#)

Form 510

[Chemical Manufacturer](#)
[Chemical Importer](#)
[Chemical Exporter](#)
[Chemical Distributor](#)

Active Military Only

[Military Form 224](#)

Form 363

[Narcotic Treatment Clinics](#)

DEA Proposed Rules



- The rules pertaining to EMS use of controlled substances is still pending the final ruling.
- The draft of those rules can be found here

<https://www.federalregister.gov/documents/2020/10/05/2020-21675/registering-emergency-medical-services-agencies-under-the-protecting-patient-access-to-emergency>

- These rules will govern the day to day operations as they pertain to controlled substances.
- This will be important for EMS agencies to understand moving forward.

How to view the ambulance CSR rule changes



Current View

The rule is LSA Document #20-455. Either use the link or you can search via the LSA website.

<http://iac.iga.in.gov/iac//irtoc.htm?lsayear=20&lsadoc=455&view=list&ldn=Y>

On or after August 25, 2021

Go to <http://iac.iga.in.gov/iac/> and search IAC Cite along the left column

Search for 856 IAC 2. The entire section will download and you can look for amendments for 856 IAC 2-3-4 and 856 IAC 2-3-5 and new section 856 IAC 2-3-4.5

Indiana EMS 836 Administrative Code Article 2



- In addition to federal laws and rules, Indiana EMS provider agencies will need to assure continued compliance with Indiana 836 administrative code article 2.
 - All scheduled medications shall be stored in a locked container within a locked compartment.
 - Medication storage shall be approved in writing by medical director or issuing pharmacy.
- It is a requirement to list approved controlled substances for certification and then comply with the approved list for daily operations for both Advanced EMT and paramedic provider agencies.

Additional Considerations



- Indiana Board of Pharmacy may require inspections of facilities and vehicles for all new applicants and then once every 2 years with the renewal of the CSR. Items to be addressed may include:
 - Controlled substances AND any other medications that are in the vicinity.
 - Protocol authorization to carry medications and controlled substances.
 - Expiration dates on existing stock and ask for the monitoring schedule / policy from the EMS agency.
 - Tracking system or policy to account for possession of medications at all times.
 - Destruction policies for controlled substances.
- Policies to address non-EMS certified vehicles that may carry controlled substances or on a person offsite the organization property (e.g. SWAT Medic)
- IDHS may continue to inspect controlled substances, including policies, procedures and storage during their routine EMS agency inspections.

Summary



- The “Protecting Patient Access to Emergency Medications Act of 2017 (the Act)” does several things
 - Adds EMS agencies as a new category of DEA registrants;
 - Permits the EMS agency to obtain one DEA registration for each state where the EMS agency operates;
 - Allows hospital-based EMS agencies to operate using the hospital’s DEA registration;
 - Delineates the circumstances where EMS personnel may administer controlled substances outside the physical presence of a medical director or authorizing medical professional; and
 - Provides for recordkeeping, security, and storage requirements specific to EMS agencies.
 - Recent changes to the Indiana Board of Pharmacy regulations allow EMS provider agencies to obtain a State of Indiana CSR. This is first required in order to obtain a federal DEA registration.