

EMSWORLD[®] EXPO

In Partnership With



October 10–14, 2022

EMSWORLD[®] EXPO

In Partnership With
NAEMT



Protecting Patient Access to Emergency Medication Act of 2017 (PPAEMA)



Christopher von Zwehl
CIO/ Rx Security Expert, Scripps Safe, Inc.

Faculty Disclosure

This session and content provided herein is for informational purposes only and is not a DEA or CDC funded or sponsored event. The advice/ guidance provided in this webinar consists of information to instill best practices and compliance in providing adherence to the Protecting Patient Access to Emergency Medications Act of 2017.

Specific questions regarding this Act that are DEA related questions should be directed to the nearest DEA diversion field office, competent counsel or professionally qualified consultant.





Speaker Bio

Christopher von Zwehl is the **Chief Innovation Officer at Scripps Safe**. He is one of the nation's leading experts in Rx Security Solutions. His successful career is backed by a BBA from Hofstra University and MA from The New School University. Mr. von Zwehl completed leadership & officer's training at the U.S. Coast Guard Academy and has spent 19 years as a highly decorated officer in the U.S. Coast Guard Auxiliary. Mr. von Zwehl was just awarded the 2021 Annual President's Award from the National Association of State Controlled Substances Authorities (NASCSA) and is a national speaker on fighting the opioid crisis.



Learning Objectives

After attending this presentation, the participant should understand:

1. The pros and cons of securing your own DEA controlled substances registration to procure, store, dispense and account for your own narcotics usage and inventory.
2. How to obtain your own DEA controlled substances registration.
3. How to meet all the DEA registration requirements once you are operational.
4. Learn perational integration considerations.
5. Understand State versus Federal laws. Which do I follow?



Outline/ Lesson Plan

Senior Level EMS Compliance Mgt.:

- New Independent Operations DEA Registrant Requirements for Controlled Substances Management, Implementation, Integration, Compliance and Standard Operating Procedures Overview including benefits and pitfalls.
- DEA Proposed Rulemaking Becoming Law-Registering Emergency Medical Services Agencies Under the Protection to Patient Access to Emergency Medications Act of 2017 (Hudson Act) RIN 1117-AB37/Docket No. DEA-377
- Scripps Safe will present on expanded access to controlled substances by emergency medical services agencies for administration to patients during emergencies.
- Presenter will address point by point the regulations to prevent controlled substance diversion with specific recommendations to comply and with such.
- Consideration and implementation of best practices that will provide greater control, transparency and accountability by the emergency services agencies storing, inventorying, dispensing, administering, and disposing of the controlled substances they handle.



Summary Points of the PPAEMA for EMS



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



Summary Points of the PPAEMA for EMS, Cont'd.

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



Summary Points of the PPAEMA for EMS, Cont'd.

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



Summary Points of the PPAEMA for EMS, Cont'd.

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.



The pros and cons of securing your own DEA controlled substances registration to procure, store, dispense and account for your own narcotics usage and inventory

Pros

Cons



How to obtain your own DEA controlled substances registration

*You are already licensed and certified
with your state and accrediting agency.
Now what?*

A quick guide to the DEA Office of
Diversion Control website to becoming
a new registrant



**How to meet proposed DEA
registration requirements
once you are operational**



*What does it take to maintain a DEA
registration in good standing?*



Operational Integration Considerations

1. Designated Locations
2. Service Vehicles
3. Record Keeping Requirements
4. Restocking
5. Maintenance of Records
6. Security Controls
7. Storage of Controlled Substances
8. Delivery of CSA's
9. Administration
10. Standing Versus Verbal Orders



State Versus Federal Laws. Which do I follow?

*The stricter/ higher level of
compliance of the two.*





Closing Remarks

*Where Does The PPAEMA Stand Today in
Becoming Codified?*

chrisvz@scripps-safe.com

www.4SafeRx.com

1-844-4Safe-Rx (472-3379)



References & Acknowledgments

1. Protecting Patient Access to Emergency Medications Act of 2017
2. Department of Justice Drug Enforcement Administration 21 CFR Parts 1300, 1301, 1304, 1306, and 1307 [Docket No. DEA-377] RIN 1117-AB37
3. DEA Office of Diversion Control Website: <https://www.deadiversion.usdoj.gov/>
4. Summary Points By:

Emily Sargent, CDC Public Health Law Program intern and JD and MPH candidate at the Indiana University Robert H. McKinney School of Law and the Indiana University Richard M. Fairbanks School of Public Health, with the assistance of Gregory Sunshine, JD, public health analyst, Cherokee Nation Assurance, and Matthew Penn, JD, MLIS, director, Public Health Law Program (PHLP) within the Centers for Disease Control and Prevention's Center for State, Tribal, Local, and Territorial Support.



EMSWORLD[®] EXPO

In Partnership With
NAEMT 

