



OLD DOMINION EMERGENCY MEDICAL SERVICES ALLIANCE

MEMORANDUM

TO: EMS Agency Administration and Leadership
FROM: Heidi M. Hooker, Executive Director
DATE: October 30, 2024
SUBJECT: Updated Timeline and Requirements for Regional Drug Box Program Transition

This memo provides updated and clear information regarding the transition from the regional drug box program. It includes revised timelines, regulatory updates, and essential actions for EMS agencies to take for a smooth transition.

Once again, we are very grateful to our hospital partners for their continued support. The regional drug box program has operated successfully for 40 years, and we appreciate their efforts to extend the program past the initial transition date of November 12, 2024, to allow all agencies to transition away from the regional program.

Updated Transition Timeline

DEA and FDA Regulatory Changes

- **FDA:** On October 9, 2024, the FDA issued an exemption from the enhanced drug distribution security requirements of section 582 of the FD&C Act for eligible trading partners, extending the compliance date for one year to November 27, 2025.
- **DEA:** It's expected that the DEA's anticipated enforcement of the Protection of Patient Access to Emergency Medications Act may be released sometime in 2025.

Transition Update and Future Timeline

- **October 28, 2024:** The Virginia Regional EMS Medication Kit Transition Workgroup met to discuss the extension. The workgroup proposed an **April 15, 2025**, drug box program transition date.
- **October 30, 2024:** ODEMSA and hospital partners agreed to extend the transition deadline to the proposed **April 15, 2025** date.
- *Should the DEA publish its final rule for the Protection of Patient Access to Emergency Medications Act with an enforcement date before April 15, 2025, the transition date will be adjusted to the earlier of the two dates.*

Current Compliance Status

As of the most recent review, the compliance status for ODEMSA agencies is as follows:

Board of Pharmacy Controlled Substance Registrations

- **34 ALS agencies** have successfully obtained a CSR.
- **12 ALS agencies** are partnering with another agency to obtain drugs under the hub-and-spoke model.
- **7 ALS agencies** have Board of Pharmacy (BOP) inspections pending.
- **5 ALS agencies** are awaiting the results of their BOP inspections.

- **6 ALS agencies** are currently unable to submit CSR applications.
- **2 ALS agencies** are transitioning from ALS Non-Transport to BLS Non-Transport.
- **1 ALS agency** is transitioning from ALS Transport to BLS Transport.
- **17 BLS agencies** are determining whether they require a CSR.
- **1 BLS Non-Transport agency** holds a valid CSR.

Drug Enforcement Administration Registrations

- **14 ALS agencies** are awaiting a CSR before submitting their DEA application.
- **10 ALS agencies** have received a CSR but have not submitted their DEA application.
- **10 ALS agencies** are under DEA application review and awaiting approval.
- **14 ALS agencies** have successfully obtained a DEA Registration.
- **12 ALS agencies** are partnering with another agency to obtain drugs under the hub-and-spoke model.
- **4 ALS agencies** are currently unable to submit DEA applications.
- **2 ALS agencies** are transitioning from ALS Non-Transport to BLS Non-Transport and will not pursue DEA registrations.

Key Actions

Agencies Operating Under Individual Programs

Agencies should continue to work on the following:

- Obtaining a Controlled Substances Registration (CSR)
- Obtaining an agency DEA license
- Developing agency-specific plans
- Establishing drug purchasing agreements (CSOS or DEA 222)
- Develop a timeline to include:
 - Stocking of drug supplies
 - Successfully pilot an agency drug box program, ideally without comingling agency and regional programs. These steps will ensure that policies and workflows are tested and fully operational before the agency fully transitions from the regional system.

Even with the extension, agencies should transition to agency-based programs as soon as possible.

Please note that there is ongoing discussion regarding whether agencies with DEA registrations may still participate in the regional program. Agencies may need a **DEA 222 form** for each Schedule II transfer. We are actively seeking clarification on this matter and will provide further information as it becomes available.

Transition Readiness Updates

- Agencies should **submit monthly status updates to ODEMSA** to track CSR, DEA registration, and purchase agreements. This information will be shared with multiple partners across the region and the Commonwealth in an effort to cut down on agencies having to contact multiple entities to update them.

Ordering Controlled Substances

- While **CSOS (Controlled Substances Ordering System)** is preferred, **DEA 222 forms** can serve as an option if the distributor agrees.
- For questions, about the DEA 222 or CSOS, please contact your sales representative or distributor for guidance.

Transition Support

- Any agency experiencing difficulties meeting the April 15, 2025, deadline should contact ODEMSA immediately to address obstacles and develop solutions to overcome them.

Next Steps and Support

Agencies planning to transition to their drug box program **before April 15, 2025, MUST notify ODEMSA of their intent** and provide a transition date and details before making the switch.

Please keep the following updated points in mind during your transition:

- **Early Transition:** If an agency transitions prior to the April 15, 2025, deadline, the agency will take ownership of the drug boxes in their possession. Agencies will have to complete a form attesting that they will not exchange medications at a hospital and acknowledge the transition to an agency-based program.
- **Return Scheduling:** If you do not require “stocked” ODEMSA drug boxes, please coordinate with ODEMSA in advance to schedule a location, date, and time for return. If you have extra unstocked boxes that you do not require, please contact ODEMSA. This is to allow boxes to be reallocated to agencies that will continue using the Flambeau boxes for their program.
- **Box Labeling and Markings:** Upon completion of an agency’s transition, **all ODEMSA labels and markings MUST be removed.**

Please continue working closely with ODEMSA for guidance and support during this process. If you have any concerns or require assistance, contact the ODEMSA office directly.