

Date: April 10, 2023

System Memo: # 417

To: All System members

From: Matthew T. Jordan, MD, FACEP  
EMS System Medical Director

Connie J. Mattera, MS, RN, PM  
EMS Administrative Director

RE: **Controlled Substance Log compliance data**

Our sincere thanks to the PBPI committee for assessing and measuring our quality performance and compliance data in helping us achieve our EMS System goals and adherence to regulatory standards.

**Attached to this memo are the Controlled Substance Log data for 2022 and 2023 to date** so you have the needed information to affirm and celebrate best practices with your teams or to ask the right questions and set action plans in place where indicated.

**THANK YOU to all who have achieved 100%** accuracy and timely report submission.

According to the data submitted so far, a few agencies have performance gaps, but we have full confidence that can be remedied. **We are asking for your help and cooperation in bringing us to full conformity ASAP.**

### Why is this important?

## Northwest Community Healthcare

September 5, 2019

EMS Replenishment  
Internal Audit Report

Privileged and Confidential Communication: Produced at the Direction of Legal Counsel

Several of you are new to your roles since the System experienced a Controlled Substance audit in 2019.

They found 9 areas of risk identification. One was relative to **Controlled Substance Logs**

### Findings

Controlled substance logs, used to document the daily quantity of controlled substance on EMS vehicles, were inconsistently documented and reviewed.

- During testing, there were two days from the 14 selected controlled substance logs where there was no sign-offs from the EMS personnel to validate their count.
- EMS personnel were performing more than one count in a row without another personnel's inspection.
- Four of the 14 controlled substance logs also had no evidence of review from the EMS Coordinator and the controlled substance logs from July had not been obtained or reviewed by the EMS Coordinator three weeks into August.

Per Controlled Substances on EMS Vehicles Policy, controlled substance logs should be filled out daily by two EMS personnel and reviewed for missing counts, signatures, or EMS personnel performing more than one count in a row by the second week of the subsequent month.

### Risk Cause/Details

Controlled substances may be diverted and not detected.

Operation of the Control: Staff are not held accountable for not consistently documenting and reviewing the controlled substance logs.

### NCH Action Plan

4a. The EMS Administrative Director will recommunicate to all EMS personnel performing controlled substance counts or reviews the Controlled Substances on EMS Vehicles Policy which outlines that controlled substance logs must be utilized to document the count of controlled substances by two EMS personnel.

4b. The EMS Administrative Director will recommunicate to the EMS Coordinators the Controlled Substances on EMS Vehicles Policy which outlines that all controlled

substance logs must be reviewed for missing counts, signatures, or EMS personnel performing more than one count in a row without another personnel's inspection.

4c. The EMS Administrative Director will update the controlled substance log procedures to state that controlled substance logs must be reviewed monthly by the EMS Coordinator by the fourth week of the subsequent month.

**Action Plan Owner(s)** Connie Mattera, Administrative Director, EMS  
**Action Plan Due Date** December 31, 2019

**The System complied with the initial action plan findings by updating the C6 policy, doing extensive CE, and changing the Logs, but nonconformities remain.**

<b>Northwest Community EMS System</b>		<b>POLICY MANUAL</b>	
<b>Policy Title: EMS CONTROLLED SUBSTANCE (CS) Program Rev 2-6-20</b>		<b>No.</b>	<b>C - 6</b>
<b>Board approval:</b> 1/9/20	<b>Effective:</b> 3/1/20	<b>Supersedes:</b> 6/10/18	<b>Page:</b> 1 of 7

**LEGAL and REGULATORY REQUIREMENTS:** The procurement, prescribing, administration, and transfer of CS are highly regulated by federal and state laws and regulations, as well as compliance standards (Joint Commission and Centers for Medicare and Medicaid Services). The possession and administration of controlled substances is governed by the U.S. Department of Justice Drug Enforcement Administration. This policy establishes the EMS standards for management of Controlled Substances (CS) by NWC EMSS agencies, hospitals, and personnel in accordance with Federal DEA Rules and Regulations. The Federal Rules are found in the Code of Federal Regulations (Title 21 CFR, Part 1300-1399), the Controlled Substance Act, and Public Law 115-83 Nov. 17, 2017 131 STAT. 1267 Protecting Patient Access to Emergency Medications Act of 2017 (PPAEMA). See the DEA website. [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

**DEA REGISTRATION:** The DEA requires that each site that stores or dispenses CS be registered. Before 2017, an EMS agency was authorized to administer CS under the DEA registration of the EMS medical director overseeing the agency's patient care. Language added by PPAEMA now allows EMS agencies to receive their own DEA registration to administer controlled substances.

At the same time our audit findings were being processed in the fall of 2019, the Federal government published Rules to implement the **“Protecting Patient Access to Emergency Medications Act (PPAEMA) of 2017”**

**This Act** is an amendment to the Controlled Substances Act and does several things

- Adds EMS agencies as a new category of DEA registrants
- Permits an 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.**

In emergency medicine (and all administration and use of controlled substances in schedules II, III, IV, or V), practitioners must track, carefully store, and report controlled substances. According PPAEMA, an agency must store drugs in a location that is registered with the DEA. Paramedics must maintain controlled substance records, outlining the inventory, storage, administration, and discarding of drugs.

**Failure to properly track or report the use of controlled substances can lead to the loss of licensure and the forfeiture of access to controlled substances, legal ramifications, and significant fines.** Per the DEA, violations of the recordkeeping requirements subject DEA registrants to civil monetary penalties of up to \$14,520 for each violation. In some cases, with several violations, this could result in fines adding up to thousands of dollars. See: <https://www.ems1.com/technology/articles/what-emergency-providers-need-to-know-about-the-deas-drug-schedule-LUBZJ1WGu7kvLUGM/>

Again, our thanks to all System members for your careful attention to this critical area of our practice. Please reach out if you have any questions, comments, or concerns and we are happy to assist.