

NWC EMSS February CE Q&A

- Q:** On slide 30 (List of issues for action plans) - regarding the audit findings...one of the bullet points states "undocumented replenishment of EMS meds from pharmacy dept." -- Can you clarify this specifically? I have never received medication directly from the pharmacy so I'm unsure of how to document this. Is it on ImageTrend somewhere? Can you give me an example of a time when we would get meds directly from the pharmacy...and how we even do that?

A: The example we were given was an agency that came directly to pharmacy and wanted to exchange multiple expired EpiPens. First, we don't stock EpiPens, so they should not have been exchanged. Second, the pharmacy did not keep a record of the agency nor the reason for the restock, so the findings from the auditor was directed two ways: an agency asking for a medication not listed on the Drug and Supply List; and the Pharmacy needed to put in place a tracking System when giving drugs to EMS personnel.

Under the new policy, EMS agencies are to follow the hospital exchange procedures as specified by the hospital. The only time EMS may be directed to the pharmacy is if they are bringing in expired or soon to expire drugs, but please follow guidelines posted by the hospital. Each hospital is currently in the process of writing and distributing their policies.

- Q:** Regarding storage of the CS in the ambulance. According to the policy C6, section C, part 3...storage of CS in a drug bag is OK as long as they are stored separate from the other medications and there is a tamper detectable plastic tie on it. My understanding is that is an acceptable "first" measure of security/lock for the CS meds. The second security measure would be the drug box/bag is kept in a locked ambulance. I seem to remember there being discussion of a 3rd requirement for the CS meds being locked, but I don't see how that is feasible when the ambulance is out of quarters or parked at the hospital, parked on a call, etc? Or am I possibly misunderstanding the need for a 3rd security measure?

A: In looking at the new Federal EMS Controlled Substance Act, it does not REQUIRE or stipulate the additional layers of protection, but multiple articles written as "best practice" models by prominent EMS Medical Directors around the country do. Required practice is to also ensure that ambulances are locked when out of quarters and that is the 3rd layer of requested protection. As you could see in the slide examples, some agencies take this far further with multiple layers of locked pouches, bags and cabinets. We are staying with the minimum protections required by law and will rely on our agencies to monitor compliance.

- Q:** On the CS log sheets, the signature lines end with "change initials." Can you explain what this means exactly and when the medics are to be initialing there?

A: If a drug count or drugs present must change within a day, such as a hospital could not stock midazolam due to a drug shortage, and EMS had to carry diazepam as an approved alternative drug, the change in stock numbers for midazolam and diazepam would be reflected and the initials of the personnel who attest to the new count are entered. Otherwise, that column may remain blank.

- Q:** If you have a controlled substance that breaks/spills, but is not used for patient care, how (or is it required) for EMS documentation of this, or is it ONLY documented in the hospital records? From what I understand in the policy, there are 2 situations...if there is some recoverable product, that is to be brought to the ER for the nurses to waste, but when we get a new vial/ampule, etc, how do we document this? When it is tied to a patient, we document on the PCR in ImageTrend, but if it is not associated with a patient, how do we document/track this exchange? Second, the policy says "if no product is recoverable, document the circumstances in the controlled substance log." -- Is this the daily log we sign when we do the controlled substance check at the beginning of shift? If so, where/how are we documenting on this form? There is no designated area for notes/comments.

A: If this is not associated with a patient to document in the narrative section of the PCR, complete an RFC and attach it to the Controlled Substance Log for the month. The RFC should be provided to the hospital EMSC where the drug is exchanged. The hospital will also be logging the exchange in their records.

5. The policy states have 2 paramedics that witnessed the breakage sign -- what if only one paramedic witnesses the event? For example, the driver is doing his morning check and accidentally drops a vial of a controlled substance and it breaks? If he is the only paramedic doing the morning daily check, how would a second person sign as a witness?

A: We must always have at least two paramedics available at all times when controlled substances are inspected and counted and responsibility (chain of custody) is transitioned from one shift or crew to another. A driver ALONE, may NOT do a morning check. These daily checks must be done by two paramedics (one offgoing and one oncoming) SIMULTANEOUSLY – and they both sign the log at the same time when the check is done.

6. **Q:** If we need to exchange non-CS meds from thy pyxis...say because they are expired meds, is there something specific the system would like the agency to type in for "patient information" i.e. First name = RMFD, Last name = STOCK? I know everyone seems to do it slightly different, is there a recommended way?

A: Good question - This will depend on the hospital's internal policy and I would encourage you to follow that. The System is not setting a standard here because some hospitals do not use an EMS Pyxis.

7. **Q:** If we are treating a chest pain patient with ASA, and we accidentally drop one of the ASA, so we open a 5th to administer to the patient. Should the 5th ASA be documented as XXFD STOCK (or equivalent) or be recorded/tied to the patient when we go to replenish the other 4 ASA?

A: My recommendation would be to note in the PCR narrative that a 5th ASA was opened due to contamination and simply add it to the restock requested for that patient.

8. **Q:** CS policy – page 6, letter "b": Provide drug in original packaging to PEMSC or supervisor who shall bring it to agency's assigned System hospital pharmacy for assay, wasting and restocking. We discussed the transporting of CS and I thought there was a point made that BC's etc could not transport CS in their agency vehicles as those vehicles are not considered ALS vehicles and while that officer may be on the agency's "list" of addl personnel (besides ALS medics assigned to the ambulance) who can have access to CS, that such transport was not allowed unless the agency had their own DEA registration instead of that under the EMS MD.

A: You are correct. How they bring the drug to the ED will vary based on their local situation of DEA registration and we need to improve clarity here. I am revising the permanent policy slightly to allow for hospital variation in terms of where possibly tampered drugs should be brought and by whom based on their DEA registration status and hospital policy:

Immediately notify the PEMSC or agency supervisor who shall ensure that the drug is brought in its original packaging to the agency's assigned System hospital pharmacy or EMS Coordinator (per hospital policy) for assay, wasting, and restocking. The mode of transport will depend on the Agency's DEA registration status. If not independently registered, the drug must remain under the custody of two paramedics on an agency vehicle documented in the EMS System plan. If independently registered, the drug may be transported by personnel and within vehicles identified in the DEA registration application.

9. **Q:** Slides 32, 33, 34 – I wrote on my speaker notes “Fail”. Did we fail at all of these requirements?

A: They are the points that must be discussed and monitored in a controlled substance management policy. Did we get cited for things within these policy provisions? Yes. Our specific citations are listed on the one slide.

10. **Q:** Slide 34 – My notes say we had no documentation of internal monitoring of compliance. Is that where the closer scrutiny by the PEMSC of the CS logs, followed by scrutiny by the HEMSC, came from?

A: Yes, along with insufficient monitoring at the hospital in the form of signatures when bringing drugs in for waste; and audits of the Pyxis machine. Please just review the 9 points for which we were cited.

11. **Q:** Slide 69: once drug replacement is completed in PCR, is this screen something that automatically displays?

A: Yes.

12. For private providers: If the ALS car is a day car and doesn't work 24 h, how is the chain of custody to be tracked? If the car say goes down at 8 pm and re-ups at 6 am who should sign and where should the CS be kept during that “off period” to minimize access? Page 3, D-4 talks about OOS and an agency specific med management plan, does that get approved by the system? What does it look like?

A: All controlled substances must have an unbroken 24/7 chain of custody. If a day car goes down at 8 pm and that crew leaves, the controlled substances must be locked up in a substantially constructed cabinet within the ambulance quarters where only qualified and credentialed ALS staff has access to them. The offgoing crew must sign off that they are relinquishing responsibility for the drugs to someone at the agency who must be responsible for the overnight security and that signature must be on the log. In the am, the oncoming paramedics must inspect the Controlled Substances stored at the agency overnight before they may be placed back on the ambulance and sign the log. If any drug is missing, tampered with or expired, the investigation will immediately begin with the last crew that signed off and the person last held responsible in the chain of custody. It is likely that we will need to create a Controlled Substance log just for this type of circumstance. All agencies have agreements with the Resource Hospital agreeing to comply with System policies. The System will need to approve a plan that does not conform to a 24/7 custody of drugs on the ambulance. It will need to be an agency-specific policy and procedure for ensuring security and oversight of controlled substances in compliance with the C6 policy.

13. Additionally on p. 4/7 E-3 it discusses that the agency needs to keep a CSL, but then on p.6 III b-3 says the hospital needs to keep the logs. Does that mean both of us need the copy?

Each party to Controlled Substance transactions is responsible for keeping their own records. Thus, EMS will have their records within the Image Trend software and our daily Controlled Substance inspections/counts and RFCs that document breakage and/or missing drugs.

Hospitals will also have their logs of CS drugs being dispersed to EMS.

14. The slide also talks about other information found after the policy which talks about (as well as we discussed in the meeting) the IL law of keeping logs for 5 years. Just for clarity, we will then need to follow IL law with the higher timeframe?

Yes, we need to follow Illinois law when it expands upon Federal law. The policy has been revised to reflect the 5 year time frame along with a couple of paragraphs updates emphasizing that EMS personnel must follow hospital-specific policies and procedures. See attached. We will also update the logs to reflect the correct time frame. Will post ASAP.