Ambulance Replenishment: DEA and DSCSA Pending Requirements

I. Controlled Substances Ambulance Restocking: DEA Considerations

The DEA allows EMS units to obtain controlled substances through the following procedures and in the listed order of preference:

A. The Protecting Patient Access to Emergency Medications Act (PPAEMA) of 2017 amended Section 33 of the Controlled Substance Act (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. **The final rule is currently pending, but with increase in DEA resources expected final rule will be published late 2023/early 2024.** The following are highlights derived from the CDC Public Health Gateway focusing on how the PPAEMA affected controlled substances and EMS services.[5] Below is an excerpt from the CDC brief.

1. **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 separately
   - This registration is completed on DEA form 224. The EMS applicant will choose "mid-level practitioner" and under this choice the applicant will choose "Ambulance Service."

2. **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." To do so, the EMS agency must:
   - Ensure that the state law authorizes standing orders
   - Actually have a standing order in place or verbal order from a medical director or an authorizing medical professional.

3. **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.

4. **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 (i.e. DEA Form 222). This does not preclude the need for completion of the DEA Form 222 if the agency is purchasing from a

wholesaler or directly from a manufacturer. **NOTE: The Virginia Board of Pharmacy is not anticipating that this provision will be allowed under the final rule.**

5. **Maintenance of Controlled Substance Records.** EMS agencies must follow record requirements stated in the CSA. These requirements include recording all deliveries of controlled substances and storing records in the locations where controlled substances are received, administered, and discarded.

6. **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. 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.

B. Hospital/Clinic Registration: There are two ways to supply a vehicle with controlled substances under this procedure. First, the emergency vehicle can be operated/owned by the hospital and supplied by the hospital pharmacy or hospital emergency room as an extension of the hospital. Second, a private emergency medical service may enter into a formal written agreement with *one specific hospital* to supply the EMS unit with a prepared emergency kit and replenish the kit as necessary.

1. An EMS squad that transports patients to multiple hospitals may only have controlled substances replaced at a base hospital. The base hospital will need a copy of the EMS trip sheet with the patient's name, date/time the controlled substance medication was administered, and the drug name/strength and how it was administered.
2. The controlled substances kit is not necessarily an exchange kit system. Controlled substances may be replaced as used and replaced back into the EMS squad stock.

II. Drug Supply Chain Security Act (DSCSA) Considerations for Ambulance Restocking (effective 11/1/24). Applies to CII-VI medications, but CII-V medications will also need to comply with DEA regulation.

The following is a snippet from the FDA DSCSA document titled "Guidance for Ambulance Restocking (Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act — Compliance Policy Guidance for Industry."[8]

> FDA understands that some dispensers, such as hospital pharmacies, provide prescription drugs to first responders for use in the emergency treatment of ill or injured persons – often in small quantities or on a periodic basis – and that such dispensers may lack the resources to provide product tracing information for these transactions. FDA also understands that some first responders may not meet the definition of "authorized" dispensers under section 581(2) of the FD&C Act because they do not have a valid license under state law. Nevertheless, they may be authorized, in accordance with applicable law, to administer certain products without a license,

such as pursuant to proscribed standards of practice and medical treatment protocols. FDA also recognizes that first responders may lack the resources to comply with certain requirements under section 582(d) of the FD&C Act, including receipt, capture and maintenance of product tracing information and verification.

To minimize possible disruptions to the activities of first responders, FDA does not intend to take action against certain trading partners and first responders as described below. This compliance policy is in effect until further notice by FDA.

Trading Partners (ex. Hospital or other dispensers supplying medications to ambulance):

- FDA does not intend to take action against a dispenser who **transfers ownership** of product directly to a first responder where the dispenser does not provide the first responder with product tracing information (i.e., a transaction information, transaction history, and transaction statement), as required by sections 582(c)(1)(A)(ii)-(iv) and (d)(1)(A)(ii) of the FD&C Act, provided that:

  - the dispenser captures and maintains the product tracing information for such transaction (including the creation of the product tracing information, prior to, at the time of transaction, or, if necessary shortly thereafter) for not less than six years after the transaction, as required under sections 582(c)(1)(A)(v) and (d)(1)(A)(iii) of the FDC& Act; and
  - the dispenser provides such product tracing information to the first responder or Secretary, if requested, not later than two business days after receiving the request or in such other reasonable time as determined by the Secretary, based on the circumstances of the request.

- FDA also does not intend to take action against a trading partner that transfers ownership of a product to a first responder who is not "authorized" as a dispenser within the meaning of section 581(2)(D) of the FD&C Act.

First Responders:

- FDA does not intend to take action against a first responder who:
  - accepts ownership of product without first receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act and does not capture and maintain product tracing information as required by section 582(d)(1)(A)(iii) of the FD&C Act; or
  - does not have systems in place to enable the verification of suspect and illegitimate product as required by section 582(d)(4) of the FD&C Act.
- If a first responder believes it has received suspect or illegitimate product, FDA strongly recommends that the first responder take steps to protect patients from receiving illegitimate product, which includes quarantine and investigation of such

product, contacting appropriate authorities, and working with the previous owner to prevent further distribution of such product.

- This compliance policy does not extend to the other requirements of section 582, including the requirement that the first responder conduct business only with authorized trading partners under section 582(d)(3) of the FD&C Act. In addition, this compliance policy does not extend to any other requirement of the FD&C Act that may apply, including sections 503 and 583.

Impact on Current Drug Box Exchange Program in Virginia

With the current EMS drug exchange program, there is not clear ownership of the EMS box contents. To comply with both DEA and DSCSA regulation, the EMS agency must be the owner of the medications contained in the EMS box-the contents must be transferred to the agency. The new process will require each agency to hold a Virginia Board of Pharmacy Controlled Substance Registration (CSR) and a DEA license and to be the owner of the contents of the drug box.

Per the Board of Pharmacy, they do not anticipate that the DEA rule will allow 1:1 replenishment of CII-V medications once the rule is published.

1:1 replenishment of CVI to comply with DSCSA will be allowed with transfer of product to the ownership of the EMS agency if all conditions of DSCSA EMS restocking language are met.

Once the DEA rule is finalized, the current drug exchange process will put hospital DEA licenses at risk due to non-compliance. Risk could include monetary penalties and action against DEA license.

Recommendation

1. Work to ensure all EMS agencies obtain a Virginia Controlled Substance Registration (CSR) and DEA license in order to implement process required to be compliant with federal law and regulation (DEA, DSCSA)
2. Convene a stakeholder workgroup (hospitals, EMS agencies) to develop a playbook for implementation with implementation no later than 11/1/24 (DSCSA effective date). Utilize policies and practices from other states as model.

Appendix

The Anti-Kickback Statute and Ambulance Restocking

Anti-Kickback Statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce the referral of business by a federal health care program. Ambulance restocking arrangements implicate the anti-kickback statute because the receiving hospital gives something of value (drugs or medical supplies) to a potential source of Federal health care program business – ambulance providers that deliver patients to the hospital.

Since restocking arrangements serve a significant public interest enabling ambulances to depart the hospital ready for the next emergency call, the Department of Health and Human Services (HHS) published a final rule in the December 4, 2001 issue of the Federal Register, describing safe-harbor protections for ambulance restocking.[1] The final safe harbor regulations established broad protection for most existing ambulance restocking arrangements, while precluding protection for any abusive arrangements that use targeted or selective restocking for the purpose of inducing or rewarding referrals.

The final rule addresses three categories of restocking[1]

- General restocking (whether free or for a charge)
- Fair market value restocking
- Government-mandated restocking

<u>General Restocking[1]</u>

This safe harbor for general restocking is available for free restocking arrangements, as well as arrangements under which the ambulance provider pays some amount for the restocked drugs and supplies.

- The receiving facility must restock drugs or supplies on an equal basis for ambulance providers in one or more of three categories: all ambulance providers; all non-profit and governmental providers or all non-charging providers (typically volunteer and municipal providers)
- The restocking must be conducted publicly. To be considered conducted publicly the arrangement is memorialized in a conspicuously posted writing that outlines the terms of the restocking program or the restocking program operates in accordance with a plan or protocol of general application by an EMS council. The first condition may be achieved by posting a written disclosure notice at the receiving facility, with copies available to the public upon request.

<u>Fair Market Value Restocking[1]</u>

This category protects restocking arrangements where an ambulance provider pays the receiving facility fair market value, based on an ***arms-length transaction*** for restocked medical supplies. Fair market value should be measured in terms of prices the ambulance provider would pay for like supplies if purchased them from a seller for whom the ambulance provider is not a potential referral source. Restocking at prices below fair market value is not protected by this safe harbor category but may be covered by one of the other categories. For consistency with the Prescription Drug Marketing Act and some State laws, the final regulations do not include the resale of drugs in this category. (Restocking of drugs may be covered under other safe harbor categories.)

> *Per Cornell Law Legal Information Institute: "Arm's length" is an expression which is commonly used to refer to transactions in which two or more unrelated and unaffiliated parties agree to do business, acting independently and in their self-interest.*[2]

Government-Mandated Restocking[1]

This final safe harbor protects restocking of drugs and supplies undertaken in accordance with State or local statute, ordinance, regulation or binding protocol that requires hospitals to restock ambulances that deliver patients to the hospital with drugs or medical supplies that are used during the transport of that patient.

Nothing in the safe harbor regulations precludes State and local ambulance governments from regulating ambulance restocking. The OIG saw little risk under the anti-kickback statute if the State or local law or regulation is duly promulgated and the restocking is conducted in accordance with the regulations.

There are four conditions that apply to all three of the categories:[1]

1. Appropriate billing of Federal health care programs. The ambulance provider and the hospital may not both bill for the same restocked drug or supply.
2. Either the hospital or the ambulance provider may generate the necessary documentation, so long as the other party receives and maintains a copy for 5 years which is consistent with the recordkeeping requirements of the Centers for Medicare and Medicaid Services' (CMS). This document is usually referred to as a trip or run sheet, where patient care during the transport is recorded. This information must include patient information, drugs and supplies used on the patient. Some states require these documents to be maintained a longer period of time.
3. No ties to referrals. So, this mean that referrals are not "conditioned on, or otherwise takes into account, the volume or value of any referrals or other business generated between the parties for which payment may be made in whole or in part by a Federal health care program (other than the delivery to the receiving facility of the particular patient for whom the drugs and medical supplies are restocked."[1]

4. Compliance with all other Federal, State and local laws, including the handling of controlled substances. Please note the D.E.A. requirements listed at the end of this section.

Additional Information from the Final Rule

- The proposed rule required the safe harbor restocking arrangements be memorialized in writing in a plan or protocol of general application or a written contract or agreement between the parties…BUT…. Under the final rule, no particular form of writing is mandated.[1] The writing can take the form of a simple disclosure statement. A sample disclosure statement is available in an appendix to part 1001, subpart C of the regulation. Regulatory department has also attached a copy of the sample disclosure on Attachment A.[3]

- Expanded the safe harbor to include restocking for non-emergency runs so long as the ambulance is also used for emergency runs.[1] The new regulations provide that an ambulance will satisfy this standard if the ambulance is used to respond to emergencies an average of three times per week measured over any reasonable time period. For example, if an ambulance is used twelve times for emergency runs during a month, the test will be met.

Additionally, on March 24, 2003, the OIG issued program guidance for ambulance suppliers.[4]

- Restocking must be accurately documented using EMS trip sheets (run sheets), patient care reports, patient encounter reports, or other documentation that records the specific type and amount of drugs or supplies used on the transported EMS patient and subsequently restocked.

- The pharmacy must maintain a copy of the EMS trip sheet (EMS version of a Medication Administration Record) with the record of medications replaced to the EMS. These records must be maintained for five years.

- Under the Medicare program, in almost all circumstances the ambulance supplier – not the hospital - will be the party entitled to bill for the restocked supplies or drugs used in connection with an ambulance transport, even if they are obtained through a restocking program.

Attachment A
Title 42, Chapter V, Subchapter B, Part 1001, Subpart C Appendix A to Subpart C of Part 1001.[3]

The following is a sample written disclosure for purposes of satisfying the requirements of § 1001.952(v)(3)(i)(B)(1)(i) of this part. This form is for illustrative purposes only; parties may, but are not required to, adapt this sample written disclosure form.

Notice of Ambulance Restocking Program

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers (other than ambulance providers that do not provide emergency services) that bring patients to Hospital X [or to a subpart of Hospital X, such as the emergency room] in the following category or categories: [insert description of category of ambulances to be restocked, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and Government ambulance providers]. [Optional: We only offer restocking of emergency transports.]

2. The restocking will include the following drugs and medical supplies, and linens, used for patient prior to delivery of the patient to Hospital X: [insert description of drugs and medical supplies, and linens to be restocked].

3. The ambulance providers [will/will not] be required to pay for the restocked drugs and medical supplies, and linens.

4. The restocked drugs and medical supplies, and linens, must be documented as follows: [insert description consistent with the documentation requirements described in § 1001.952(v). By way of example only, documentation may be by a patient care report filed with the receiving facility within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.]

5. This restocking program does not apply to the restocking of ambulances that only provide non-emergency services or to the general stocking of an ambulance provider's inventory.

6. To ensure that Hospital X does not bill any Federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any Federal health care program. Participating ambulance providers must agree to work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.

7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.

8. For further information about our restocking program or to obtain a copy of this notice, please contact [name] at [telephone number].

Dated:____

/s/____

Appropriate officer or official

References:

1. "Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute." Federal Register. Vol. 66, No. 233. December 4, 2001. OIG: Rules and Regulations. Retrieved June 12, 2023. Retrieved from https://oig.hhs.gov/documents/compliance/847/restocking_final_rule.pdf.
2. "Arm's Length." Cornell Law Legal Information Institute. Last updated May 2022. Retrieved June 12, 2023. Retrieved from https://www.law.cornell.edu/wex/arm%27s_length#:~:text=%E2%80%9CArm%27s%20length%E2%80%9D%20is%20an%20expression,and%20in%20their%20self%2Dinterest.
3. "Notice of Ambulance Restocking Program." Title 42, Chapter V, Subchapter B, Part 1001, Subpart C Appendix A to Subpart C of Part 1001. Code of Federal Regulations (CFR). Last updated December 4, 2001. Retrieved June 12, 2023. Retrieved from https://www.ecfr.gov/current/title-42/chapter-V/subchapter-B/part-1001/subpart-C/appendix-Appendix%20A%20to%20Subpart%20C%20of%20Part%201001.
4. "OIG Compliance Program Guidance for Ambulance Suppliers." Federal Register, Vol. 68, No. 56. March 24, 2003: OIG: Notices. Retrieved June 12, 2023. Retrieved from https://oig.hhs.gov/documents/compliance-guidance/800/032403ambulancecpgfr.pdf.
5. "The Protecting Patient Access to Emergency Medications Act of 2017" Public Health Law. Centers for Disease Control and Prevention (CDC). May 30, 2018. Retrieved on June 12, 2023. Retrieved from https://www.cdc.gov/phlp/docs/brief-ema.pdf.
6. "Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017: Proposed Rule." DEA. Published October 5, 2020. Retrieved on June 12, 2023. Retrieved from https://www.federalregister.gov/documents/2020/10/05/2020-21675/registering-emergency-medical-services-agencies-under-the-protecting-patient-access-to-emergency#footnote-16-p62642.
7. "Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act — Compliance Policy Guidance for Industry." FDA. Published February 2017. Retrieved on June 12, 2023. Retrieved from https://www.fda.gov/files/drugs/published/Requirements-for-Transactions-with-First-Responders-under-Section-582-of-the-Federal-Food--Drug--and-Cosmetic-Act%E2%80%94-Compliance-Policy-Guidance-for-Industry.pdf.
8. "Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act — Compliance Policy Guidance for Industry." FDA. Published February 2017. Retrieved June 12, 2023. Retrieved from https://www.fda.gov/media/96584/download.