



Section 16: Appendix 4: Medical Equipment

SECTION 16: APPENDIX 4: EMS DRUG EXCHANGE SYSTEM

Purpose

Cleveland Clinic will assist in restocking of supplies and drugs used in direct patient care by a nonprofit or governmental ambulance provider which meets the Emergency Ambulance Provider definition and the requirements as defined by the Department of Health and Human Services Office of Inspector General (OIG), Ohio State Board of Pharmacy, the Drug Enforcement Agency (DEA), The Joint Commission (TJC), and other regulatory agencies. The purpose of the restocking assistance is to ensure Emergency Ambulance Providers have adequate and appropriate supplies to provide efficient and high quality patient care so that patients arrive at the hospital in the best possible condition. Because of current DEA and State Board of Pharmacy rules, Emergency Ambulance Providers may not be able to purchase certain drugs from another distributor. It is an important community service for Cleveland Clinic to assist the Emergency Ambulance Providers in obtaining these necessary drugs. This policy outlines how the restocking program will be administered.

Policy

Emergency Services in the Cleveland Clinic health system (CChs) facilities will restock supplies and drugs used by an Emergency Medical Services (EMS) Provider in accordance with the Ohio State Board of Pharmacy, DEA, OIG requirements, Centers for Medicare and Medicaid Services (CMS) regulations, and all other applicable federal and state laws and regulations, in the following two scenarios: (1) in connection with the transport of a patient to the CChs Facility, or (2) for an EMS Provider for which a CChs Facility Pharmacy serves as the Medical Control Pharmacy.

The restocking will be handled consistently for all EMS Providers that qualify under this Policy (i.e., non-profit or governmental EMS Providers who have transported a patient to a CChs Facility or an EMS Provider for which a CChs Facility Pharmacy serves as the Medical Control Pharmacy).

Supplies and drugs will only be exchanged on 1:1 basis or based on a Medical Director Restocking Pharmacy Exhibit A - Emergency Medical Service Ambulance Restocking Agreement and Medical Control Agreement Restocking Pharmacy Exhibit B - Medical Control Agreement, and only upon receipt of proper documentation. Restocking must be in accordance with this Policy.

Policy Implementation Procedure

1. The Cleveland Clinic (CChs) facility and the EMS Provider must comply with the 1992 DEA letter to the Ohio State Board of Pharmacy [Restocking Pharmacy Exhibit C](#), the 2011 Letter from the Ohio Department of Public Safety, Division of Emergency Medical Services [Restocking Pharmacy Exhibit D](#) and the Ohio Hospital Association, and any subsequent applicable guidance with regard to exchange of drugs to EMS Providers.
2. Supplies and drugs, including Controlled Drug Substances, will be exchanged on a 1:1 basis or based on a Medical Director and Medical Control Agreement, and only upon receipt of the necessary documentation from the EMS Provider.
3. Only drugs listed on the EMS Provider's Addendum are eligible for restocking.
4. Supply and drug exchange will be performed by a CChs employee authorized to access medications as determined by each facility.
5. In order for the exchange to take place:



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- a. The EMS Provider and CChs Facility must execute and maintain a current EMS Ambulance Restocking Agreement and, if applicable, a Medical Director and Medical Control Agreement. These documents must be reviewed and approved by the Cleveland Clinic Law Department.
 - b. The EMS Provider cannot have an active DEA Registration if the exchange is for Controlled Drug Substances.
 - c. The EMS Provider must submit an Ohio State Board of Pharmacy-approved Patient Care Report (PCR) to the CChs Facility at the time of restocking. If the EMS Provider cannot immediately file the PCR due to a subsequent emergency call that necessitates an immediate response, the EMS Provider may file the PCR with the receiving CChs Facility within 24 hours of the delivery of the patient. The PCR sheet must have an original signature unless the EMS Provider uses an electronic medical record system that is approved by the Ohio State Board of Pharmacy, in which case an electronic signature will be acceptable.
 - d. Prior to participating in the CChs restocking program, the EMS Provider must provide copies of its Addendum and License to the CChs Facility Pharmacy and submit updated copies on an annual basis. In addition, the EMS Provider must provide copies of its standing orders or protocols and a list of the personnel employed or used by the EMS Provider to provide emergency medical services who are authorized to possess the drugs, as well as the personnel who are authorized to administer the drugs, and submit updated copies when needed. The CChs Facility Pharmacy must receive these documents prior to providing the approved drugs to the EMS Provider. If the EMS Provider receives an approval to add a new unit or drug, the EMS Provider must submit copies of the new Addendum and License to the CChs Facility Pharmacy within ten (10) days from when the EMS Provider received the updated documents.
6. The CChs facility Pharmacy will maintain updated copies of Licenses and Addendums of EMS Providers that service their area or have current Medical Director and Medical Control Agreements with the CCHS Facility, pursuant to Ohio Revised Code §§ 4729.54 and 4729.55.
 7. Each CChs facility must have a written disclosure of its ambulance restocking program [Restocking Pharmacy Exhibit E - Notice of Ambulance Restocking Program 3.27.13 final](#) which has been approved by the Cleveland Clinic Law Department and produced in conformance with the Cleveland Clinic standard signage protocols. The disclosure must be posted conspicuously in the CChs Facility's emergency room or other location where EMS Providers deliver patients. Copies must be made available upon request to EMS Providers, government representatives, and members of the public, and may be subject to reasonable photocopying charges.
 8. Each CChs facility and EMS Provider must comply with all Federal, State, and local laws and regulations pertaining to the provision of drugs and medical supplies, including the laws and regulations related to the handling of Controlled Drug Substances.
 9. If an EMS Provider is utilizing an electronic medical record for documentation, the system must be an approved system in Ohio for authenticating health care records pursuant to Ohio Revised Code § 3701.75.
 10. Whenever possible, expired drugs should be replaced from the same CChs facility where the drugs were originally supplied.



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11. The CChs facility Pharmacy must maintain records of drugs that are replaced due to breakage, expiration, or for any reason not documented on the PCR.
12. The PCR is considered a drug order and will be stored for a minimum of 5 years as required by CMS.
13. The CChs facility will not bill the patient or any payor, including any Federal health care program, for the restocked supplies or drugs.
14. The CChs facility and the EMS Provider must comply with all applicable claims filing and billing rules and regulations, including Federal health care program payment and coverage rules and regulations.
15. The restocking under this policy is in no way conditioned on, nor does it otherwise take into account, the volume or value of referrals or other business generated between the EMS Provider and the CChs facility.

Oversight and Responsibility

1. It is the responsibility of each hospital, institute, department and discipline providing direct patient care to implement the policy and to draft and operationalize related procedures to the policy if applicable.
2. The Department of Pharmacy is responsible for reviewing, revising, and updating this policy to maintain compliance with regulatory or other requirements.
3. The Department of Pharmacy is responsible for data analysis, as indicated, to drive related performance improvement initiatives.

Definitions

Cleveland Clinic health system (CChs): Main Campus, Family Health Centers, physician practice sites, and Las Vegas practice sites. Regional Hospitals (Euclid, Fairview, Hillcrest, Lakewood, Lutheran, Marymount, Medina and South Pointe), plus the Children's Rehabilitation Hospital

PCR – Patient Care Report (also known as a “runsheets”) approved by the Ohio State Board of Pharmacy

Addendum: A current Addendum to Limited License from the Ohio State Board of Pharmacy.

EMS Ambulance Restocking Agreement: See Exhibit A. EMS Ambulance Restocking Agreements must be reviewed and approved by the Cleveland Clinic Law Department.

License: A current Terminal Distributor of Dangerous Drugs License from the Ohio State Board of Pharmacy.

Medical Director and Medical Control Agreement: See Exhibit B. Medical Director and Medical Control Agreements must be reviewed and approved by the Cleveland Clinic Law Department.



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Medical Control Pharmacy: The pharmacy that serves as the responsible DEA registrant for the EMS Provider pursuant to a current Medical Director and Medical Control Agreement. The EMS Provider must provide the Medical Control Pharmacy with copies of its License and Addendum, as well as EMS drug protocols approved by the Ohio State Board of Pharmacy and authorized and signed by the EMS Provider's medical director.

Based on the OIG definitions in the Ambulance Restocking Safe Harbor under the Anti-Kickback Statute:

Emergency Ambulance Service: A transport by ambulance that results from a call through 9-1-1 or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient and available at the CChs Facility that is the receiving facility.

Emergency Ambulance Provider ("EMS Provider"): A provider or supplier of ambulance transport services that provides emergency ambulance services, including Air Medical Service. The EMS Provider must be a nonprofit or governmental organization and the ambulance must be used to respond to emergencies an average of three times per week measured over any reasonable time period.

Policy References

1. 42 CFR Part 1001 RIN 0991-AB05 Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute
2. Ohio Revised Code §§ 4729.54 and 4729.55
3. Ohio Revised Code § 3701.75