



Department of Community Health

Drug Shortages How Michigan has Addressed

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Medical Control Authority (MCA)

- Part 209 of P.A. 368 of 1978, as amended is the statute that supports Michigan's Emergency Medical Services, Medical Control Authorities, life support agencies and personnel.

Medical Control Authority

- A Medical Control Authority is an organization designated by the department for the purpose of supervising and coordinating an emergency medical services system, as prescribed, adopted, and enforced through department-approved protocols for a particular geographic region.
- A Medical Control Authority is a hospital or group of hospitals that operates a service that treats patients 24 hours a day, 7 days a week

Medical Control Authority

A medical control authority shall do all of the following:

- Develop bylaws that define the medical control authority organizational structure
- Appoint a medical control authority board to administer the medical control authority.
- Appoint an Advisory Body
- Appoint a medical director
- Appoint a Professional Standards Review Organization, for the purpose of improving the quality of medical care
- Collect data to assess the quality and needs of emergency medical services throughout its medical control authority region.

Medical Control Requirements

- MCAs are responsible for:
 - establishing written protocols for the practice of life support agencies and EMS personnel.
 - circulating draft protocols to all significantly affected persons for review, and
 - submitting to MDCH for approval
 - ensuring physicians, hospital staff, and providers are educated on protocols
 - adhere to protocols

Medical Control Requirements

- Each participating and nonparticipating hospital within a MCA region shall follow all standards, policies, procedures, and protocols established by the MCA as approved by the Department.
- Licensed life support agencies and individuals are accountable to the MCA in the provision of emergency medical services as defined in protocols.
- Protocols adopted by the MCA and approved by the department have the force and effect of law.

Medical Control Authority

- Medical control authorities are required to comply with the statute and with the promulgated rules.
- A MCA shall establish written protocols for the practice of life support agencies and licensed emergency medical services personnel.
- State Protocols have been developed for MCAs to utilize. Adoption of state protocols, allows for consistency and reduces review time for protocols.

MCA Emergency Protocol

- A Medical Control Authority may establish an emergency protocol necessary to preserve the health or safety of individuals within its jurisdiction in response to a medical emergency...without following the normal review procedure.
- A protocol established under this is effective only for a limited time period and does not take permanent effect unless approved by the Department.

Emergency Medication Shortage Protocol

The purpose of this protocol is to address the National Shortage of specific medications. This protocol authorizes the substitution of the Zofran, Benzodiazepine & Fentanyl options previously selected by a Medical Control Authority that are currently on file with the State of Michigan.

Medical Control Authorities choosing to adopt this Emergency Protocol may do so. Per Administrative Rule 325.22206 Rule 207 (5) an emergency protocol shall remain in effect for 60 days unless approved by the department.

OR

Medical Control Authority may choose to adopt as a Medication Shortage Procedure.

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Emergency Medication Shortage Protocol

- The Michigan Protocols for Adult & Pediatric Treatment call for the selection of one (1) Benzodiazepine medication.
 - Emergency protocol allows for selecting all options.
- The Patient Sedation Procedures allow for multiple selections.
 - Emergency protocol allows for an MCA to make further selections in the event the options selected are affected by the medication shortage.
- The Narcotic options in the state Pain Management Procedure allow for multiple selections.
 - Emergency protocol allows for an MCA to make further selections in the event the options selected are affected by the medication shortage.
- The Emergency protocol allows for an MCA to make selection of Zofran ODT as an alternative to Zofran IV/IM in the event IV Zofran availability is affected by the medication shortage.

Alternative Medication Shortage Management Policy

Due to frequent and on-going medication shortages for protocol medications an MCA developed a process for the use of alternate medications or alternate dosing in the event of medication shortages, recalls or lack of availability in our current protocol concentrations.

This protocol is being used to develop a State Protocol that an MCA can adopt immediately.

Alternative Medication Shortage Management Policy

Alternate Doses

- Medications may be substituted for a different concentration of the same medication provided the dose on hand does not exceed what is approved in treatment protocols/medication contents lists. In these instances, while the concentration or container for the medications may be different, no change will be made to the medication dose to be delivered to a patient.



Alternative Medication Shortage Management Policy

Alternate Medications

Alternate medications include all medications not currently listed in the protocols

- Examples: Diazepam and Midazolam become temporarily unavailable, Lorazepam (Ativan) is subsequently approved as an alternative.
- When an alternate is already approved by the state as a potential selection, but your MCA has not adopted that medication, each MCA may submit the Medication Shortage Supplement to the state indicating the adoption of the previously unchecked medication to include the date of adoption and if the adoption will be temporary or permanent. If permanent, the emergency protocol will take effect immediately, however; a revised protocol that follows the state protocol review and approval process must be submitted.

Alternative Medication Shortage Management Policy

- Alternate medications, not already contained in state approved protocols, may be submitted on the Medication Shortage Supplement to the state as an emergency protocol but may not be adopted until approved by the department.
- A state issued emergency protocol may be adopted to address widespread shortages.
- Alternate medications will be signified by the placement of a sticker, tag or label on the outside of the bag or box; on the compartment where the alternate medication is located (if applicable) such that one inspecting the bag or box could easily recognize that the medication was included and what the missing medication it is intended to replace was.

Alternative Medication Shortage Management Policy

Missing Medication

- Missing medications are those which, due to short supply, are not available to be placed into a bag or box but which are required by protocol. In these cases, efforts will be made to place alternate medications in the bag or box.
- Missing medications will be signified by the placement of a sticker, tag or label on the outside of the bag or box, on the compartment where the missing medication would be located (if applicable) such that one inspecting the bag or box could easily recognize that the medication was missing and what the potential alternate medication was.

Alternative Medication Shortage Management Policy

Process:

- A brightly colored ALTERNATE DOSE sticker MUST be attached to the outside of the drug bag, box or narcotics box that lists the effected medication, the concentration of the substituted medication and the expiration date of the medication.
- A brightly colored – MISSING MEDICATION sticker must be placed on bags/boxes when a protocol medication is not available to stock in that bag/box.
- A dosing chart may be required to be included in the bag/box depending on the change.
- Pharmacies experiencing shortages must provide notification of the need to utilize alternate dosing to the MCA and the drug exchange coordinator, and receive approval, prior to any change being implemented.

Alternative Medication Shortage Management Policy

- Drug bags, boxes or narcotics boxes with alternate dose medications/missing medications should have the medication replaced and the sticker/tag removed by pharmacy as soon as possible when the proper medication or concentration of medication is available.
- Any additional equipment that is needed to deliver the medication must be included with the alternate dose. (I.e. – Medication is typically in a carpupject but a vial is being substituted due to shortages of the carpupject version. An appropriately sized safety needle and syringe must be available within close proximity to the medication in order to facilitate administration. These supplies too may be removed when the proper medication concentration is returned to the bag/box.)

Alternative Medication Shortage Management Policy

- EMS Agencies receiving notice of the utilization of alternate dosing, alternate medications or missing medications due to shortage must post the changes and ensure that all providers that may have cause to use the medications are made aware of the changes and are educated on proper use, risk and dosing of any new or replacement medication prior to their first potential exposure to the alternate dose or medication.
- Given the frequency and the expectation that these shortages will continue to occur, we cannot stress the need to verify medications enough. EMS providers **MUST** ensure that they are giving the **RIGHT MEDICATION**, in the **RIGHT DOSAGE**, using the **RIGHT ROUTE**, and are given to the **RIGHT PATIENT**.
- Any Special Instruction for a particular shortage will be communicated to all effected pharmacies and EMS services.

Questions?

